80-482

Nos. 80-483

Supreme Court, U.S.
FILED
SEP 25 1980
MICHAEL RODAK, JR., CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1980

LEAD INDUSTRIES ASSOCIATION, INC., *Petitioner,*

v.

ENVIRONMENTAL PROTECTION AGENCY, *Respondent.*

ST. JOE MINERALS CORPORATION, *Petitioner,*

v.

ENVIRONMENTAL PROTECTION AGENCY, *Respondent.*

APPENDIX TO PETITIONS FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

EDWIN H. SEEGER
CARL B. NELSON, JR.
PRATHER SEEGER DOOLITTLE & FARMER
1101 Sixteenth Street, N.W.
Washington, D. C. 20036
(202) 296-0500

Attorneys for Petitioner Lead Industries Association, Inc.

JOHN MCN. CRAMER
REED SMITH SHAW & MCCLAY
747 Union Trust Building
Pittsburgh, Pa. 15219
(412) 288-3131

LEE A. RAU
ROBERT A. EMMETT
DANIEL A. MASUR
REED SMITH SHAW & MCCLAY
1150 Connecticut Avenue, N.W.
Washington, D. C. 20036
(202) 457-6100

Attorneys for Petitioner St. Joe Minerals Corporation

September 25, 1980

PRESS OF BYRON S. ADAMS PRINTING, INC., WASHINGTON, D.C.

TABLE OF CONTENTS

PAGE

APPENDIX A

Opinion of the Court Below 1a

APPENDIX B

EPA's Final Air Quality Standards for Lead, 43 Fed. Reg. 46246, October 5, 1978 ..... 113a

APPENDIX C

Excerpt from Testimony of Dr. Herbert L. Needleman, February 15, 1978 ..... 167a

APPENDIX D

Excerpt from Testimony of Dr. Sergio Piomelli, January 31, 1977 ..... 169a

Notice: This opinion is subject to formal revision before publication in the Federal Reporter or U.S.App.D.C. Reports. Users are requested to notify the Clerk of any formal errors in order that corrections may be made before the bound volumes go to press.

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 78-2201

LEAD INDUSTRIES ASSOCIATION, INC., PETITIONER

v.

ENVIRONMENTAL PROTECTION AGENCY, RESPONDENT
BUNKER HILL COMPANY, INTERVENOR

No. 78-2220

ST. JOE MINERALS CORPORATION, PETITIONER

v.

ENVIRONMENTAL PROTECTION AGENCY, RESPONDENT
BUNKER HILL COMPANY, INTERVENOR

Petitions to Review Action of the
Administrator of the Environmental Protection Agency

Argued November 7, 1979

Decided June 27, 1980

Bills of costs must be filed within 14 days after entry of judgment. The court looks with disfavor upon motions to file bills of costs out of time.

Edwin H. Seeger, with whom *Gary M. Welsh* and *Richard T. Witt* were on the brief, for petitioner in No. 78-2201 and for intervenor in both cases.

Robert A. Emmett, with whom *John McN. Cramer* was on the brief, for petitioner in No. 78-2220.

James N. Cahan, Attorney, Environmental Protection Agency, and *Michael P. Carlton*, Attorney, Department of Justice, with whom *Sanford Sagalkin*, Acting Assistant Attorney General, *Angus MacBeth*, Attorney, Department of Justice, *Joan Z. Bernstein*, General Counsel, Environmental Protection Agency, and *Gerald K. Gleason*, Deputy Associate General Counsel, Environmental Protection Agency, were on the brief, for respondent. *James W. Moorman*, Attorney, Department of Justice, and *Jeffrey O. Cerar*, Attorney, Environmental Protection Agency, also entered appearances for respondent.

David Schoenbrod for *amici curiae* Natural Resources Defense Council, Inc. *et al.* urging affirmance in both cases.

Kathleen W. Mikkelson, Deputy Attorney General, State of California, was on the brief for *amicus curiae* Air Resources Board, State of California, urging affirmance in both cases.

Before WRIGHT, *Chief Judge*, and ROBINSON and MACKINNON, *Circuit Judges*.

Opinion for the court filed by *Chief Judge* WRIGHT.

WRIGHT, *Chief Judge*: This is the third occasion on which this court has been asked to review Environmental Protection Agency (EPA or Agency) regulations promulgated under authority of the Clean Air Act, as amended, 42 U.S.C. § 7401 *et seq.* (Supp. I 1977) (the Act), and specifically designed to deal with the health problems associated with lead in the ambient air. In *Amoco Oil Co. v. EPA*, 501 F.2d 722 (D.C. Cir. 1974),

we upheld regulations prohibiting the sale of leaded gasoline for use in automobiles equipped with "catalytic converter" devices for controlling exhaust emissions and requiring widespread retail marketing of at least one grade of unleaded gasoline. And in *Ethyl Corp. v. EPA*, 541 F.2d 1 (D.C. Cir.) (*en banc*), *cert. denied*, 426 U.S. 941 (1976), we affirmed an EPA order requiring annual reductions in the lead content of leaded gasoline. In the present consolidated cases we are asked to review EPA regulations establishing national ambient air quality standards for lead. These air quality standards prescribe the maximum concentrations of lead that will be permitted in the air of our country. We must decide whether EPA's Administrator acted within the scope of his statutory authority in promulgating these regulations and, if so, whether the evidence adduced at the rulemaking proceeding supports his final determinations. In addition, we must examine the petitioners' claims that infirmities in the procedures employed by EPA in this rulemaking warrant remand of the regulations to the Agency. Petitioners are the Lead Industry Association, Inc. (LIA), a nonprofit trade association whose 78 members include most of the country's producers and commercial consumers of lead (No. 78-2201), and St. Joe Minerals Corporation (St. Joe) (No. 78-2220).[1]

I. Background

Man's ability to alter his environment to achieve perceived goals has undoubtedly made an enormous contribution to his economic and social well-being. This undertaking is not, however, without attendant costs. One of these costs is the toll that these alterations may exact

---

[1] The Bunker Hill Company is an intervenor, and the Natural Resources Defense Council, Inc. and the Air Resources Board of the State of California were granted permission to participate as *amici curiae*.

on the environment itself and, in turn, the dangers that this may pose for the public health and welfare. Unfortunately, man's ability to alter the environment often far outstrips his ability to foresee with any degree of certainty what untoward effects these changes may bring. The issues presented by these cases illustrate this sad fact.

Lead's environmental significance is a consequence of both its abundance and its utility. The relative abundance of lead in the earth's crust makes it unique among the toxic heavy metals. EPA's "Air Quality Criteria For Lead" (hereinafter cited as CD) 1-1, Joint Appendix (JA) 1105. And centuries of mining and smelting, and the use of lead in a variety of human activities, have increased the natural background concentration of lead in the environment. *Id.* But it is only since the industrial age and the use of lead as a gasoline additive that lead has become pervasive. *Id.* at 1-2 - 1-3, JA 1106-1107. Today lead is ubiquitous. It is found in almost every medium with which we come into contact—food, water, air, soil, dust, and paint, *id.* 1-1, JA 1105, each of which represents a potential pathway for human lead exposure through ingestion or inhalation. The widespread presence of this toxic metal in the environment poses a significant health risk. Lead is a poison which has no known beneficial function in the body, *id.* 1-12, JA 1116, but when present in the body in sufficient concentrations lead attacks the blood, kidneys, and central nervous and other systems and can cause anemia, kidney damage, severe brain damage, and death. *Id.* 1-6 - 1-9, JA 1110-1113.[2]

There are three major sources of the body's lead burden. In most people the largest source is diet. CD 7-9,

---

[2] *See generally* EPA's "Air Quality Criteria For Lead" (hereinafter cited as CD), Chapter 11, JA 1223-1276.

JA 1179.[3] Another source, particularly in children, is the habit of placing hands, objects, and materials in the mouth.[4] The third major source is the ambient air; airborne lead is deposited in the respiratory tract as a person breathes lead-contaminated air and is subsequently absorbed into the bloodstream. CD 1-5, JA 1108. Once the lead is in the bloodstream its source is immaterial; total lead intake is the sum of the intake from all these sources. The multiplicity of sources of lead intake increases the difficulty of controlling human lead exposure. Much of the protective activity in this area has focused on limiting the amount of lead in the ambient air, the most controllable source of lead exposure. In this country, by far the largest source of lead emissions—accounting for 88 percent of total lead emissions according to EPA estimates—is the exhaust of motor vehicles powered by gasoline containing lead additives. CD 5-3, JA 1140. Another eight percent of lead emissions is the result of solid waste incineration and combustion of waste oil. *Id.* Industrial facilities account for the remaining four percent of total lead emissions. *Id.*

Acting pursuant to authority conferred on it by Congress in the Clean Air Act, as amended, 42 U.S.C. § 7401 *et seq.*, EPA has been involved in regulation of lead emissions almost since the Agency's inception.[5] Its initial

---

[3] Estimates of daily lead intake from diet in adult males range between 100 to 500 grams/day. Only a fraction of the lead ingested is actually absorbed. CD 7-9, 10-1 - 10-4, JA 1179, 1212-1215.

[4] Pica, the habitual ingestion of nonfood substances, is a particularly important source of lead exposure for children who live in urban areas. CD 1-5, JA 1109.

[5] EPA and other federal agencies, including the Department of Housing and Urban Development, the Occupational Health and Safety Administration, and the Consumer Product Safety Commission, are involved in a variety of regulatory efforts aimed at controlling other sources of lead exposure. *See* 43 FED. REG. 46256-46257, JA 2958-2959.

approach to controlling the amount of lead in the ambient air was to limit lead emissions from automobiles by restricting the amount of lead in gasoline. To this end it promulgated the regulations which we upheld in *Amoco Oil Corp. v. EPA*, *supra*, and *Ethyl Corp. v. EPA*, *supra*. However, in 1975 the Natural Resources Defense Council, Inc. (NRDC), and others brought suit against EPA claiming that the Agency was required by Section 108 of the Clean Air Act, 42 U.S.C. § 7408, to list lead as a pollutant for which an air quality criteria document would be prepared, and for which national ambient air quality standards should be promulgated under Section 109 of the Act, 42 U.S.C. § 7409. The District Court agreed with NRDC and directed the Administrator to list lead as a pollutant under Section 108 of the Act, by March 31, 1976. *Natural Resources Defense Council, Inc. v. Train*, 411 F.Supp. 864 (S.D. N.Y. 1976). The Second Circuit affirmed, 545 F.2d 320 (1976), and EPA initiated the proceedings outlined in the statute which are under review here.

II. The Statutory Scheme

The first step toward establishing national ambient air quality standards for a particular pollutant is its addition to a list, compiled by EPA's Administrator, of pollutants that cause or contribute to air pollution "which may reasonably be anticipated to endanger public health or welfare[.]" Section 108(a)(1), 42 U.S.C. § 7408(a)(1). Within twelve months of the listing of a pollutant under Section 108(a) the Administrator must issue "air quality criteria" for the pollutant. Section 108 makes it clear that the term "air quality criteria" means something different from the conventional meaning of "criterion"; such "criteria" do not constitute "standards" or "guidelines," but rather refer to a document to be prepared by EPA which is to provide the scientific basis for promul-

gation of air quality standards for the pollutant. This criteria document must "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities." Section 108(a)(2), 42 U.S.C. § 7408(a)(2).

At the same time as he issues air quality criteria for a pollutant, the Administrator must also publish proposed national primary and secondary air quality standards for the pollutant. Section 109(a)(2), 42 U.S.C. § 7409(a)(2). National primary ambient air quality standards are standards "the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health." Section 109(b)(1), 42 U.S.C. § 7409(b)(1). Secondary air quality standards "specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air." Section 109(b)(2), 42 U.S.C. § 7409(b)(2). Effects on "the public welfare" include "effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being." Section 302(h), 42 U.S.C. § 7602(h). The Administrator is required to submit the proposed air quality standards for public comment in a rulemaking proceeding, the procedure for which is prescribed by Section 307(d) of the Act, 42 U.S.C. § 7607(d).

Within six months of publication of the proposed standards the Administrator must promulgate final primary and secondary ambient air quality standards for

the pollutant. Section 307(d)(10), 42 U.S.C. § 7607(d)(10). Once EPA has promulgated national ambient air quality standards, responsibility under the Act shifts from the federal government to the states. Within nine months of promulgation of the standards each state must prepare and submit to EPA for approval a state implementation plan. Section 110(a)(1), 42 U.S.C. § 7410(a)(1). These state implementation plans must contain emission limitations and all other measures necessary to attain the primary standards "as expeditiously as practicable," but no later than three years after EPA approval of the plan, and to attain the secondary standards within a reasonable period of time. Section 110(a)(2)(A) & (B), 42 U.S.C. § 7410(a)(2)(A) & (B). The Administrator is authorized to extend the deadline for attainment of the primary air quality standards by two years, but thereafter it must be met. Section 110(e), 42 U.S.C. § 7410(e).

III. The Lead Standards Rulemaking Proceedings

As required by statute, EPA's first step toward promulgating air quality standards for lead was to prepare a criteria document. The Lead Criteria Document was the culmination of a process of rigorous scientific and public review, and thus is a comprehensive and thoughtful analysis of the most current scientific information on the subject. The Lead Criteria Document went through three major drafts, and three separate reviews, including public meetings by the Subcommittee on Scientific Criteria for Environmental Lead of EPA's Science Advisory Board (SAB Lead Subcommittee).[6] The Agency reviewed

---

[6] This Subcommittee was composed of individuals with extensive expertise in various fields relevant to the task of preparing the Lead Criteria Document, including toxicology, environmental medicine, environmental health engineering, epidemiology, and chemical engineering. A list of the members of the Subcommittee and their credentials appears in the Criteria Document. CD v, JA 1085.

over 280 public comments, most of a sophisticated scientific nature, before it issued the final Criteria Document. Members of the public, industry (including the petitioners in these cases), environmental groups, the scientific community, and state and federal government agencies actively participated in the review of the drafts. Notice of the meetings of the SAB Lead Subcommittee was published in the *Federal Register*, and the drafts of the Criteria Document which were to be reviewed were available before the meetings. A formal record and a transcript of the proceedings were kept, and a review of the transcript shows that scientists with differing views could —and did—exchange ideas with each other as well as agency staff, and that all were questioned by the members of the Subcommittee.

A. *The Lead Criteria Document* [7]

EPA released its "Air Quality Criteria For Lead" on December 14, 1977. 42 FED. REG. 63076, JA 1480. The

---

[7] The first draft of the Criteria Document was released for public comment on November 18, 1976. This draft was severely criticized for its lack of scholarship, poor analysis, and low overall quality by most of the experts who reviewed it. By a 4-3 vote the SAB Subcommittee adopted a resolution that the draft's fundamental flaws made it an inadequate basis for future drafts and recommended that EPA prepare an entirely new draft. JA 268-270. The second draft of the Criteria Document was released on May 27, 1977 and, while the reaction to it was slightly more favorable, the SAB Subcommittee concluded that the draft was inadequate as a basic scientific support document for development of health-related air quality standards. JA 821-824. The third draft of the Criteria Document was released on August 22, 1977, and this time the consensus of the SAB Subcommittee was that the draft was basically sound and represented a vast improvement over the previous drafts. JA 935, 1069-1073. The Subcommittee agreed that another meeting to review the final draft of the Criteria Document was unnecessary. Instead, each individual member would submit written com-

document was "prepared to reflect the current state of knowledge about lead—specifically, those issues that are most relevant to establishing the objective scientific data base that will be used to recommend an air quality standard for lead that will adequately safeguard the public health." CD 1-1, JA 1105. Accordingly, the Criteria Document examined a large number of issues raised by the problem of lead in the environment. One of these was the effects of lead exposure on human health. The Criteria Document concluded that, among the major organ systems, the hematopoietic (blood-forming) and neurological systems are the areas of prime concern. CD 1-12, JA 1116. Its discussion of the effects of lead on these two organ systems is central to our review of the lead standards.[8]

The Criteria Document identified a variety of effects of lead exposure on the blood-forming system. We will discuss only the effects that played an important role in the Administrator's analysis. Anemia, which can be caused by lead-induced deformation and destruction of erythrocytes (red blood cells) and decreased hemoglobin synthesis,[9] is often the earliest clinical manifestation of

---

ments, if any, on the final draft. In his final report to the Agency the chairman of the Subcommittee stated that on the whole the final draft "accurately reflect[ed] the available scientific literature and provid[ed] an adequate scientific basis for promulgation and issuance of a standard for airborne lead." JA 913-914. The only other comments on the final draft were from two consultants retained by the Subcommittee who found the draft sound on many points but declined to endorse it because they disagreed with some of its conclusions. JA 915-920, 2107-2114.

[8] Lead also affects the renal, reproductive, endocrine, hepatic, cardiovascular, immunologic, and gastrointestinal systems. CD Chapter 11, JA 1223-1276.

[9] Hemoglobin is the protein which transports life-sustaining oxygen from the respiratory system to all cells in the body. CD 11-8, JA 1230. It consists of a combination of heme

lead intoxication. CD 11-7 - 11-8, 11-13, JA 1229-1230, 1235. Symptoms of anemia include pallor of the skin, shortness of breath, palpitations of the heart, and fatigability.[10] The Criteria Document concluded, after a review of various studies, that in "children, a threshold level for anemia is about 40 u[g] Pb/dl, whereas the corresponding value for adults is about 50 ug Pb/dl." CD 11-13, JA 1235. (The concentration of lead in the blood is measured in micrograms of lead per deciliter of blood—ug Pb/dl.)

The Criteria Document also examined other more subtle effects on the blood-forming system, associated with lower levels of lead exposure. The most pertinent of these "subclinical" [11] effects for purposes of these cases is lead-related elevation of erythrocyte protopophyrin (EP elevation).[12] According to the Criteria Document, this phe-

---

and globin, and lead interferes with hemoglobin synthesis by inhibiting synthesis of the globin moiety and affecting several steps in synthesis of the heme molecule. *See* CD 11-13 - 11-14, JA 1235-1236.

[10] STEDMAN'S MEDICAL DICTIONARY 94 (Unabridged Lawyers' Edition 1961).

[11] According to the Criteria Document, "subclinical" effects "are disruptions in function, which may be demonstrated by special testing but not by the classic techniques of physical examination; using the term 'subclinical' in no way implies that those effects are without consequences to human health." CD 13-4, JA 1334. STEDMAN'S MEDICAL DICTIONARY, *supra* note 10, defines "subclinical" as "[d]enoting a period prior to the appearance of manifest symptoms in the evolution of a disease." *Id.* at 1433.

[12] A major function of the hematological system is the production of red blood cells (erythrocytes) which carry oxygen to the cells of the body by chemically binding oxygen to the protein hemoglobin, one of the components of erythrocytes. *See* note 9 *supra*. Heme, one of the components of hemoglobin, is formed through a series of biochemical steps

nomenon must, for a number of reasons, be regarded as an indication of an impairment of human health. CD 11-11, JA 1233. First, EP elevation indicates an impairment in the functioning of the mitochondria, the subcellular units which play a crucial role in the production of energy in the body, and in cellular respiration. CD 1-6, 11-11, 11-14, 13-5, JA 1110, 1233, 1236, 1335. Second, it indicates that lead exposure has begun to affect one of the basic biological functions of the body—production of heme within the red blood cells.[13] Heme is critical to transporting oxygen to every cell in the body. Third, EP elevation may indicate that any reserve capacity there may be in the heme synthesis system has been reduced. CD 11-11, JA 1233. Finally, the Criteria Document noted that lead's interference with the process of heme synthesis in the blood may suggest that lead interferes with production of heme proteins in other organ systems, particularly the renal and neurological systems. CD 11-11, JA 1233. The Criteria Document reported that the threshold for EP elevation in children and women is at blood lead levels of 15-20 ug Pb/dl, and 25-30 ug Pb/dl in adult males. CD 13-8 (Table 13-2),

---

(heme synthesis), the final step in which is incorporation of iron into the protein protopophyrin IX. This process takes place in the mitochondria of the cell, and one of the ways in which lead affects heme synthesis is by interfering with this final step. The result is that protopophyrin IX, without iron, is incorporated in the hemoglobin molecule in the erythrocytes. Then phenomenon is detected as an elevation of protopophyrin in the erythrocyte, *i.e.*, EP elevation. CD 11-7 - 11-14, JA 1229-1236.

[13] *See* note 12 *supra*. Lead also interferes with heme synthesis by inhibiting production of an enzyme which acts as a catalyst in an early step in production of heme. *See* CD 11-8 - 11-10, JA 1230-1232. Although the threshold for detection of inhibition of this enzyme is about 10 ug Pb/dl, the Criteria Document concluded that this effect should not be considered a physiological impairment until blood lead concentrations reach levels of 40 ug Pb/dl. CD 1-6, 11-10, JA

JA 1338 (Table 13-2). While suggesting that some of the initial hematological effects of lead exposure may constitute relatively mild effects at low blood lead levels, the Criteria Document concluded that "they nevertheless signal the onset of steadily intensifying adverse effects as blood lead elevations increase. Eventually, [these] * * * effects reach such magnitude that they are of clear-cut medical significance as indicators of undue lead exposure." CD 1-13, JA 1117. The Criteria Document did not identify a particular blood lead level at which regulatory response was appropriate, but it did note with approval the 1975 guidelines issued by the Center For Disease Control, which use elevated EP at blood lead levels of 30 ug Pb/dl as the cut-off point in screening children for lead poisoning. CD 13-5, JA 1335.

The Criteria Document also examined the effects of lead exposure on the central nervous system. Among the most deleterious effects of lead poisoning are those associated with severe central nervous system damage at high exposure levels. The Criteria Document noted that neurological and behavioral deficits have long been known to be among the more serious effects of lead exposure, but it pointed out that there is disagreement about whether these effects are reversible, and about what exposure levels are necessary to produce specific deleterious effects. CD 11-14, JA 1236. Much of the impetus for the debate on these questions has been provided by the continual emergence of new information suggesting that lead exposure levels previously thought to be harmless actually cause significant neurological damage. *Id.* The more severe neurological effects of high level lead exposure are the clinical syndrome of lead encephalopathy. Early symptoms include dullness, restlessness, irritability, headaches, muscular tremor, hallucinations, and loss of memory. These symptoms rapidly progress (sometimes within 48 hours) to delirium, mania, convulsions, paralysis, coma, and death. *Id.* at 11-15, JA 1237. The Criteria Document expressed particular concern that the onset of

these serious symptoms can be quite abrupt, even in the absence of prior overt or clinical symptoms of disease. *Id.* at 13-6, JA 1336. After a review of various studies, the Criteria Document concluded that the blood lead threshold for these neurological effects of high level exposure is 80-100 ug Pb/dl in children, and 100-200 ug Pb/dl in adults. *Id.* at 1-13, 11-18, 11-25, 13-6, JA 1117, 1240, 1247, 1336.

The Criteria Document also went on to consider the evidence on whether lower level lead exposures can affect the central nervous system, particularly in children. It acknowledged that the issue is unsettled and somewhat controversial, but it was able to conclude, after a careful review of various studies on the subject,[14] that "a rather consistent pattern of impaired neural and cognitive functions appears to be associated with blood lead levels below those producing the overt symptomatology of lead encephalopathy." CD 1-7, JA 1111. The Criteria Document reported that "[t]he blood lead levels at which neurobehavioral deficits occur in otherwise asymptomatic children appear to start at a range of 50 to 60 ug/dl, although some evidence tentatively suggests that such effects may occur at slightly lower levels for some children." *Id.*[15]

---

[14] *See* CD 11-18 - 11-26, JA 1240-1248. Some of these studies suggested that low level lead exposure may cause central nervous system deficits, resulting in impaired concept formation and altered behavioral profiles, may interfere with the normal intellectual development of lead-exposed children, and may cause subtle neurological damage. *Id.*

[15] The Criteria Document also discussed the possibility that adverse health effects, including neurobehavioral deficits, may be induced by *in utero* exposure of the human fetus to lead. It pointed out that the potential for deleterious health effects from lead exposure in the areas of reproduction and development is particularly large, but felt that the paucity of information and confirmatory studies precluded any firm conconclusions about threshold blood lead levels. CD 11-45 - 11-58, JA 1267-1270

In addition to examining the health effects of lead exposure, the Criteria Document also discussed other issues critical to the task of setting air quality standards for lead. One of these issues is the relationship between air lead exposure and blood lead levels—a relationship commonly referred to as the air lead/blood lead ratio. The Criteria Document acknowledged that derivation of a functional relationship between air lead exposure and blood lead levels is made difficult by the fact that the relationship is not a linear one; rather, the ratio tends to increase as air lead levels are reduced, CD 12-24, JA 1311. The Document was nevertheless able to conclude, after a detailed examination of the relevant studies, CD 12-22 - 12-29, JA 1309-1316, that air lead/blood lead ratios fall within a range of 1:1 to 1:2 (ug Pb/m^3 air) : (ug Pb/dl blood) at the levels of lead exposure generally encountered by the population, *i.e.*, blood lead levels increase by between 1 and 2 ug Pb/dl of blood for every 1 ug Pb/m^3 of air. (Air lead content is measured in micrograms of lead per cubic meter of air—ug Pb/m^3.) CD 12-38, JA 1325. The Criteria Document reported that the studies indicate that the ratio for children is at the upper end of this range or even slightly above it. *Id.*

Finally, the Criteria Document also examined the distribution of blood lead levels throughout the population, concluding that there is a significant variability in individual blood lead responses to any particular level of air lead exposure. It further found that this variability is consistent and predictable, and that the application of established statistical techniques to the distribution of individual blood lead levels would make it possible to predict what proportion of the population would be above or below any particular blood lead level at a given level of air lead exposure.[16] The Criteria Document looked into

---

[16] The statistical distribution of individual blood lead levels in a homogeneous population was found to be lognormal; *i.e.*, the log values of blood lead levels would fall in the

the question whether any sub-groups within the population are particularly vulnerable to the effects of lead exposure. It concluded that preschool-age children and pregnant women are particularly sensitive to lead exposure, the latter mainly because of the risk to the unborn child. CD 13-11 - 13-14, JA 1341-1344.

B. *The Proposed Standards*

Simultaneously with the publication of the Lead Criterial Document on December 14, 1977, the Administrator proposed a national primary ambient air quality standard for lead of 1.5 ug Pb/m^3 monthly average. 42 FED REG. 63076, JA 1480. He also proposed that the secondary air quality standard be set at the same level as the primary standard because the welfare effects associated with lead exposure did not warrant imposition of a stricter standard. 42 FED REG. 63081-63082, JA 1485-1486. In the preamble to the proposed standards the Administrator explained the analysis EPA had employed in setting the standards.

The Administrator first pointed out that a number of factors complicate the task of setting air quality standards which will protect the population from the adverse health effects of lead exposure. First, some sub-groups within the population have a greater potential for, or are more susceptible to the effects of, lead exposure. *Id.* at 63077, JA 1481. Second, there are a variety of adverse health effects associated with various levels of lead exposure. *Id.* Third, the variability of individual responses to lead exposure, even within particular subgroups of the population, would produce a range of blood

---

familiar bell-shaped curve. CD 12-1, JA 1288. This means that for any given level of air lead exposure the population will have a range of blood lead levels rather than a single level, with about half the population having blood lead levels above the geometric mean and the other half below it.

lead levels at any given air lead level. *Id.* at 63079, JA 1483. Fourth, airborne lead is only one of a number of sources of lead exposure and the relative contribution from each source is difficult to quantify. *Id.* at 63080, JA 1484. Finally, the relationship between air lead exposure and blood lead levels is a complex one. *Id.* at 63079, JA 1483.

In response to the first problem the Administrator began by noting that protection of the most sensitive groups within the population had to be a major consideration in determining the level at which the air quality standards should be set. And he determined that children between the ages of 1 and 5 years are most sensitive to the effects of lead exposure both because the hematologic and neurologic effects associated with lead exposure occur in children at lower threshold levels than in adults, and because the habit of placing hands and other objects in the mouth subjects them to a greater risk of exposure. *Id.* at 63077-63078, JA 1481-1482. Next, the Administrator examined the various health effects of lead exposure and proposed that EP elevation should be considered the first adverse health effect of lead exposure because it indicates an impairment of cellular functions, and should be the pivotal health effect on which the lead standards are based. *Id.* at 63078, JA 1482. Accordingly, he proposed that the air lead standards be designed to prevent the occurrence of EP elevation in children. In order to accomplish this, and to address the problem of variable responses to lead exposure, the Administrator selected 15 ug Pb/dl, the lowest reported threshold blood lead level for EP elevation in children, as the target mean population blood lead level.[17] He reasoned that setting the

[17] The target mean population blood lead level is the blood lead level that will ensure that the great majority of the target population is protected from the adverse health effects of lead. Given the variability in individual blood lead re-

target mean population blood lead level at the lowest reported threshold blood lead level for EP elevation would ensure that most of the target population would be kept below blood lead levels at which adverse health effects occur. *Id.* at 63079, JA 1483. The Administrator also discussed the alternative approaches of basing the standard on more severe effects such as anemia, or attempting to decide the actual level of EP elevation which represents an adverse effect on health, and then making an adjustment to allow a margin of safety. *Id.* He specifically invited comments on these alternative approaches. *Id.* Finally, the Administrator outlined another approach to calculating the target mean population blood lead level involving the use of statistical techniques discussed in the Criteria Document. *Id.*[18]

Having selected a target mean population blood lead level, the Administrator's next step was to allow for the multiplicity of sources of lead exposure. He thus had to estimate the amount of blood lead that should be attributed to non-air sources. The Administrator admitted that any amount he selected could be no more than a

---

sponses to lead exposure, a population with a mean blood lead level of 15 ug Pb/dl will have individuals with blood lead levels higher and lower than 15 ug Pb/dl, but since 15 ug Pb/dl is the lowest blood lead level at which EP elevation has been detected, most children will be kept below blood lead levels at which adverse health effects occur.

[18] *See* CD 12-1 - 12-3, 12-38, JA 1288-1290, 1325. This alternative approach would use lognormal statistical procedures to determine what mean population blood lead levels would keep a specified percentage of the population below a blood lead level chosen to represent the safe blood lead blood level for the average individual. The Administrator pointed out that he had misgivings about this approach because it might overestimate the degree to which the mean population level should be below the threshold blood lead level, particularly since 15 ug Pb/dl is the lowest reported threshold blood level for EP elevation. 42 FED. REG. 63079, JA 1483.

theoretical national average, and on the basis of the evidence available he proposed that the lead standards should be based on the general assumption that 12 ug Pb/dl of blood lead should be attributed to non-air sources. *Id.* at 63080-63081, JA 1484-1485. Given the target mean population blood lead level of 15 ug Pb/dl and the assumed contribution from non-air sources of 12 ug Pb/dl, the maximum allowable contribution from ambient air is 3 ug Pb/dl. The final step in his analysis was to determine what air lead level would prevent the ambient air contribution to blood lead levels from exceeding 3 ug Pb/dl. This step required determining the relationship between air lead exposure and blood lead levels, *i.e.*, the air lead/blood lead ratio. On the basis of the information in the Criteria Document, the Administrator selected a ratio of 1:2 as appropriate for calculating the effect of air lead exposure on blood lead levels in children. *Id.* at 63079, JA 1483.

Thereafter, calculation of the air quality standard was a mathematical exercise as shown in the following table.

1. Target mean blood lead level	15 ug Pb/dl
2. Assumed non-air contribution	−12 ug Pb/dl
3. Allowable air contribution	= 3 ug Pb/dl
4. Permissible air lead concentration given assumed air lead/blood lead ratio	
$3 \text{ ug Pb/dl} \times \frac{1 \text{ ug Pb/m}^3 \text{ air}}{2 \text{ ug Pb/dl blood}}$	= 1.5 ug Pb/m^3

The Administrator concluded, on the basis of available information, that the averaging period for the lead standard should be a calendar month. *Id.* at 63081, JA 1485.

C. *Public Comments*

The public comment period ran from December 14, 1977 to March 17, 1978, and public hearings on the pro-

posed standards were held on February 15 and 16, 1978. 43 FED. REG. 46246, JA 2948. The comments on the proposed standards were sharply divided. The comments submitted by the lead industry and its experts uniformly opposed the proposed standards, and many endorsed a standard of 5 ug Pb/m^3, the standard proposed in the discredited first draft of the Criteria Document, *see* note 7 *supra*, as adequate to protect the public health. 43 FED. REG. 46248, JA 2950. On the other hand, environmental groups, medical experts, and state, local, and federal agencies either endorsed the proposed standards or called for even stricter standards. *Id.* None of the comments seriously questioned the selection of children between the ages of 1 and 5 years as the target population group, or the estimate of a contribution from non-air sources of 12 ug Pb/dl. The major areas of controversy were the Administrator's choice of EP elevation as the pivotal adverse health effect and his conclusion that the threshold blood lead level for EP elevation in children is 15 ug Pb/dl, the selection of an appropriate air lead/blood lead ratio, the appropriate allowance for an adequate margin of safety, and the averaging time period for the standards. *Id.*[19]

A number of comments challenged the selection of EP elevation as the pivotal adverse health effect, insisting that EP elevation merely indicates a biological change or response which is in no way harmful to health,[20] and in addition they criticized the Administrator's determination that the blood lead threshold for EP elevation in children

---

[19] A summary of the significant comments that were submitted and EPA's responses to them can be found in the preamble to the final regulations. 43 FED. REG. 46248-46252, JA 2950-2954.

[20] *See, e.g.*, JA 2176, 2193-2194 (statement of St. Joe Minerals Corp.); JA 1843 (statement of E. Jacobs, duPont Corp.); JA 2067 (statement of G. Ter Haar, Ethyl Corp.); JA 2388-2390, 2393 (statement of J. Jandl, LIA); JA 1773-1774 (J. Chisholm, LIA).

is 15 ug Pb/dl.[21] These comments suggested that a decrease in hemoglobin levels, which begins at blood lead levels no lower than 40 ug Pb/dl, should be the pivotal adverse health effect on which the standards are based.[22] Other experts, however, agreed with the Administrator's conclusion that EP elevation must be considered an adverse health effect of lead exposure, and argued that using EP elevation as the pivotal adverse health effect would, in addition, allow an adequate margin of safety in protecting against the more serious health effects associated with higher levels of lead exposure.[23] Finally, several industry experts appeared to indicate a preference for the lognormal statistical procedures that the Administrator had, in the proposed standards, suggested as an alternative method for determining the target mean population blood lead level.[24]

D. *The Final Air Quality Standards for Lead*

The Administrator promulgated the final air quality standards on October 5, 1978, prescribing national primary and secondary ambient air quality standards for lead of 1.5 ug Pb/m^3, averaged over a calendar quarter. 43 FED. REG. 46246, JA 2948. Although the final stand-

---

[21] *See, e.g.*, JA 1775-1779 (J. Chisholm, LIA); JA 2362-2366 (comments of LIA); JA 2492-2498 (E. Jacobs, duPont Corp.); JA 1843-1845 (statement of E. Jacobs, duPont Corp.).

[22] *See, e.g.*, JA 2193-2194 (statement of St. Joe Minerals Corp.); JA 2263-2271 (Asarco); JA 1774-1775 (J. Chisholm, LIA); JA 1831-1832 (J. Cole, LIA).

[23] *See, e.g.*, JA 2161-2167 (D. Schoenbrod, NRDC); JA 2168-2169 (H. Needleman); JA 1563-1564 (P. Landrigan, Center for Disease Control); JA 2499-2508 (S. Piomelli); JA 2580-2588 (H. Needleman and S. Piomelli); JA 2612-2614 (E. Silbergeld).

[24] *See* text and note at note 18 *supra*. *See* JA 2100-2101 (J. Chisholm, LIA); JA 2223-2224 (St. Joe); JA 2368-2369 (LIA); JA 1831-1832 (J. Cole, LIA).

ards were the same as the proposed standards (with the exception of the change in the averaging period from 30 to 90 days), the Administrator arrived at the final standards through somewhat different analysis. The preamble to the final standards reveals that the comments on the proposed standards had led the Administrator to reconsider his analysis. In particular, he seemed to feel that legitimate questions had been raised concerning the health significance of the early stages of EP elevation and about the threshold blood lead level for this condition. 43 FED. REG. 46248, 46253, JA 2950, 2955. The Administrator's reexamination focused on two key questions: (1) What is the maximum safe individual blood lead level for children? and (2) what proportion of the target population should be kept below this blood lead level? *Id.* at 46249, 46252-46253, JA 2951, 2954-2955. Addressing the first issue required a review of the health effects of lead exposure discussed in the Criteria Document. The Administrator concluded that, although EP elevation beginning at blood lead levels of 15-20 ug Pb/dl is potentially adverse to the health of children, only when blood lead concentration reaches a level of 30 ug Pb/dl is this effect significant enough to be considered adverse to health. *Id.* at 46253, JA 2955. Accordingly, he selected 30 ug Pb/dl as the maximum safe individual blood lead level for children. *Id.* The Administrator based this choice on three mutually supporting grounds. First, it is at this blood lead level that the first adverse health effect of lead exposure—impairment of heme synthesis —begins to occur in children. Second, a maximum safe individual blood lead level of 30 ug Pb/dl would allow an adequate margin of safety in protecting children against more serious effects of lead exposure—anemia, symptoms of which begin to appear in children at blood lead levels of 40 ug Pb/dl, and central nervous system deficits which start to occur in children at blood lead levels of 50 ug Pb/dl. Third, the Administrator reasoned that the maximum safe individual blood lead level should be

no higher than the blood lead level used by the Center for Disease Control in screening children for lead poisoning—30 ug Pb/dl. *Id.*

Having determined the maximum safe individual blood lead level for the target population, the Administrator next focused on the question of what percentage of children between the ages of 1 and 5 years the standard should attempt to keep below this blood lead level. According to the 1970 census, there are approximately 20 million children under the age of 5 years in the United States, 12 million of them in urban areas and 5 million in inner cities where lead exposure may be especially high. The Administrator concluded that in order to provide an adequate margin of safety, and to protect special high risk sub-groups, the standards should aim at keeping 99.5% of the target population below the maximum safe individual blood lead level of 30 ug Pb/dl.[25] *Id.* at 46253, 46255, JA 2955, 2957. The next step in the analysis was to determine what target mean population blood lead level would ensure that 99.5% of the children below the age of 5 years would be kept below the maximum safe individual blood lead level of 30 ug Pb/dl. Using the lognormal statistical technique he had alluded to in the proposed standards,[26] he calculated that a target mean population blood lead level of 15 ug Pb/dl (the same number as in the proposed standards, but arrived at through different analysis), would accomplish this task.[27]

---

[25] Some of the industry comments on the proposed standards had, in calculating alternative standards, also chosen to protect 99.5% of the target population. *See* JA 2223 (St. Joe); JA 2368 (LIA).

[26] *See* text and note at note 18 *supra.*

[27] The procedure involved determining the geometric mean blood lead level that would place 99.5% of the target population below a blood lead level of 30 ug Pb/dl (*i.e.*, given the variability in individual responses to lead exposure, *see* text

Id. at 46253, 46254, JA 2955, 2956. Thereafter, the Administrator used the same estimate of the contribution from non-air sources, 12 ug Pb/dl, and the same air lead/blood lead ratio, 1:2, that he had used in calculating the proposed standards,[28] to compute the final ambient air quality standards for lead. The result was an ambient air quality standard of 1.5 ug Pb/m^3, the same as the proposed standard. *Id.* at 46254, JA 2956. The Administrator did, however, change the averaging period for the standards from one calendar month to one calendar quarter, *id.* at 46255, JA 2957, because he felt that this change would significantly improve the validity of the data to be used in monitoring the progress toward attainment of the standards without rendering the standards less protective. *Id.*

On December 8, 1978 LIA petitioned EPA for reconsideration and a stay of the lead standards. JA 2980-3000. The Administrator denied the petition on February 2, 1979. JA 3001-3007. These petitions for review of the lead standards regulations followed. Before examining the petitioners' challenges to the regulations, we consider the limits of our reviewing function.

IV. Standard of Review

The scope of judicial review of the Administrator's decisions and actions is delineated by Section 307(d) of the Act, 42 U.S.C. § 7607(d). We must uphold the Administrator's actions unless we find that they were: (1)

---

and note at note 16 *supra*, it was necessary to base the standards on a blood lead level of 15 ug Pb/dl in order to ensure that 99.5% of the children below the age of 5 years are kept under a blood lead level of 30 ug Pb/dl). In performing the calculation the Administrator used a geometric standard deviation of 1.3. 43 Fed. Reg. 46253, JA 2955.

[28] *See* —— F.2d at —— (pp. 18-19) *supra*.

"arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law"; (2) "contrary to constitutional right, power, privilege, or immunity"; (3) "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right[.]" Section 307(d)(9), 42 U.S.C. § 7607(d)(9). In addition, we may set aside any action found to be "without observance of procedure required by law," if (i) the failure to follow the prescribed procedure was arbitrary or capricious, (ii) the procedural objection was raised during the public comment period, or there were good reasons why it was not, and (iii) the procedural errors "were so serious and related to matters of such central relevance to the rule that there is a substantial likelihood that the rule would have been significantly changed if such errors had not been made." *Id.* Section 307(d)(8), 42 U.S.C § 7607(d)(8).

These statutory provisions and a considerable body of case law demonstrate that our role as a reviewing court is limited. The "arbitrary and capricious" standard of review is highly deferential, and presumes agency action to be valid. *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971); *Ethyl Corp. v. EPA*, *supra*, 541 F.2d at 34. Moreover, the reviewing court may not substitute its judgment for the agency's, *Citizens to Preserve Overton Park, Inc. v. Volpe*, *supra*, 401 U.S. at 416, and must affirm the agency's decision if a rational basis for it is presented. *Bowman Transportation, Inc. v. Arkansas-Best Freight Systems, Inc.*, 419 U.S. 281, 290 (1974); *United States v. Allegheny-Ludlum Steel Corp.*, 406 U.S. 742, 749 (1972). Of course a reviewing court does not serve as a mere rubber stamp for agency decisions. Rather, the function of judicial review is to ensure that agency decisions are "based on a consideration of the relevant factors." *Citizens to Preserve Overton Park, Inc. v. Volpe*, *supra*, 401 U.S. at 416.

In addition, the court must undertake a "substantial inquiry" into the facts, one that is "searching and careful." *Id.* at 415, 416; *Ethyl Corp. v. EPA*, *supra*, 541 F.2d at 34. In cases such as the ones we have before us, cases which involve complex scientific and technical questions, conducting a "substantial inquiry" into the facts may require the court to delve into the scientific literature. The purpose of this scrutiny of the evidence in the record is to educate the court. As we pointed out in *Ethyl Corp. v. EPA*, *supra*, the court "must understand enough about the problem confronting the agency to comprehend the meaning of the evidence relied upon and the evidence discarded; the questions addressed by the agency and those bypassed; the choices open to the agency and those made." 541 F.2d at 36. Only by doing this can the court "penetrate to the underlying decisions of the agency, to satisfy itself that the agency has exercised a reasoned discretion, with reasons that do not deviate from or ignore the ascertainable legislative intent." *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 850 (D.C. Cir. 1970), *cert. denied*, 403 U.S. 923 (1971).[29] However, it is appropriate to sound some notes

---

[29] To be sure, *Greater Boston Television Corp. v. FCC*, 444 F.2d 841 (D.C. Cir. 1970), *cert. denied*. 403 U.S. 923 (1971), was a case involving "substantial evidence" review. However, its explication of the proper scope of a reviewing court's examination of the evidence has been adopted in a number of cases involving "arbitrary and capricious" review. *E.g.*, *Ethyl Corp. v. EPA*, 541 F.2d 1, 36 (D.C. Cir.) (*en banc*), *cert. denied*, 426 U.S. 941 (1976); *Portland Cement Ass'n v. Ruckelshaus*, 486 F.2d 375, 402 (D.C. Cir. 1973), *cert. denied*, 417 U.S. 921 (1974); *International Harvester Co. v. Ruckelshaus*, 478 F.2d 615, 648 (D.C. Cir. 1971). Moreover, this court has embraced "the emerging consensus of the Courts of Appeals that the distinction between the arbitrary and capricious standard and substantial evidence review is largely semantic[.]" *Pacific Legal Foundation v. Dep't of Transportation*, 593 F.2d 1338, 1343 n.35 (D.C. Cir. 1979). And in *Ethyl Corp. v. EPA*, *supra*, we explained that

of caution about the limits of this exercise. First, we would be less than candid if we failed to acknowledge that we approach the task of examining some of the complex scientific issues presented in cases of this sort with some diffidence.[30] More important, we stress that our review of the evidence is not designed to enable us to second-guess the agency's expert decisiomaker. *Ethyl Corp. v. EPA*, *supra*, 541 F.2d at 36. Congress has entrusted the Agency with the responsibility for making these scientific and other judgments, and we must respect both Congress' decision and the Agency's ability to rely on the expertise that it develops. *Market Street Railway v. Railroad Commission*, 324 U.S. 548, 559-561 (1945); *Ethyl Corp. v. EPA*, *supra*, 541 F.2d at 36. As we explained in *Ethyl Corp. v. EPA*:

> [A]fter our careful study of the record, we must take a step back from the agency's decision. We must look at the decision not as the chemist, biologist or statistician that we are qualified neither by training nor experience to be, but as a reviewing court exercising our narrowly defined duty of holding agencies to certain minimal standards of rationality. "Although [our] inquiry into the facts is to be searching and careful, the ultimate standard of review is a narrow one." * * * We must affirm unless the agency decision is arbitrary or capricious.

541 F.2d at 36-37 (citations and footnotes omitted; brackets in original).

---

scrutiny of even the most complex evidentiary issues is not inconsistent with the deferential standard of review, so long as the purpose of such scrutiny is to enable the court to better understand the issues before the agency. *See* 541 F.2d at 36-37.

[30] *See Portland Cement Ass'n v. Ruckelshaus*, *supra* note 29, 486 F.2d at 402; *International Harvester Co. v. Ruckelshaus*, *supra* note 29, 478 F.2d at 647.

It is also important to note that although the pertinent sections of the Clean Air Act outline the policy objectives to be sought and the procedural framework to be followed in promulgating ambient air quality standards, Congress left the formulation of the specific standards to EPA's Administrator. This task presents complex questions of science, law, and social policy under the Act. The record is lengthy—approximately 10,000 pages—and it is highly technical. The Administrator's task required both "a legislative policy determination and an adjudicative resolution of disputed facts." *Mobil Oil Corp. v. FPC*, 483 F.2d 1238, 1257 (D.C. Cir. 1973).

These are conceptually distinct types of decisions, and it is important that we keep this in mind in reviewing the Administrator's decisions. *See Industrial Union Dep't, AFL-CIO v. Hodgson*, 499 F.2d 467, 474-475 (D.C. Cir. 1974). Where factual determinations were necessary the Administrator often had to make decisions in the face of conflicting evidence. In some instances this merely required that he draw conclusions from the evidence in the record. In reviewing these conclusions we can examine the record to ascertain whether there is substantial evidence in the record when considered as a whole which supports the Administrator's determinations. *Id.* at 474. Other questions involved in the standard-setting process, however, are at the very "frontiers of scientific knowledge." [31] Consequently, the information available may be insufficient to permit fully informed factual determinations. In such instances the Administrator's decisions necessarily had to rest largely on policy judgments. Policy choices of this sort "are not susceptible to the same type of verification or refutation by reference to the record as are [other] factual questions." 499 F.2d at 475. While we will indeed scrutinize such judgments carefully, we must adopt a different mode of judicial review. *Id.; accord, Nat'l Asphalt Pavement*

[31] *See generally Ethyl Corp. v. EPA*, *supra* note 29, 541 F.2d at 24-27.

Ass'n v. Train, 539 F.2d 775, 783-784 (D.C. Cir. 1976); *Automotive Parts & Accessories Ass'n, Inc. v. Boyd*, 407 F.2d 330, 336, 338 (D.C. Cir. 1968). As this court has previously stated:

> What we are entitled to * * * is a careful identification by the [Administrator], when his proposed standards are challenged, of the reasons why he chooses to follow one course rather than another. Where that choice purports to be based on certain determinable facts, [he] must, in form as well as substance, find those facts from evidence in the record. By the same token, when the [Administrator] is obliged to make policy judgments where no factual certainties exist or where facts alone do not provide the answer, he should so state and go on to identify the considerations he found persuasive."

Industrial Union Dep't, AFL-CIO v. Hodgson, *supra*, 499 F.2d at 475-476. In short, "[t]he paramount objective is to see whether the agency, given an essentially legislative task to perform, has carried it out in a manner calculated to negate the dangers of arbitrariness and irrationality in the formulation of rules for general application in the future." *Automotive Parts & Accessories Ass'n, Inc. v. Boyd*, *supra*, 407 F.2d at 338.

Finally, although we may set aside the Administrator's decisions if we find that he exceeded his authority under the statute, we note that EPA's construction of the Clean Air Act has been accorded considerable deference by the courts. *Union Electric Co. v. EPA*, 427 U.S. 246, 256 (1976); *Train v. Natural Resources Defense Council, Inc.*, 421 U.S. 60, 75 (1975); *Ethyl Corp. v. EPA*, *supra*, 541 F.2d at 12 n.16.[32] Where different interpretations of

---

[32] Deference to EPA's interpretation is particularly warranted where, as here, the Act and its amendments were enacted with the advice and cooperation of EPA and its predecessor agencies. *See E. I. du Pont de Nemours & Co. v. Train*, 430 U.S. 112, 134-135 (1977); *Hercules Inc. v. EPA*, 598 F.2d 91, 101 (D.C. Cir. 1978).

the statute are plausible, so long as EPA's construction of the statute is reasonable we may not substitute our own interpretation for the Agency's. *Train v. Natural Resources Defense Council, Inc., supra*, 421 U.S. at 75.[33] "[T]he construction of a statute by those charged with its execution should be followed unless there are compelling indications that it is wrong[.]" *Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367, 381 (1967); *accord, Beal v. Doe*, 432 U.S. 438 (1977). Deference to the Administrator's interpretation is particularly appropriate in construing a statute that invests him with a considerable amount of discretion. Unless it can be shown that the Administrator's construction of the statute is plainly unreasonable, we must uphold his interpretation. *Motor & Equipment Manufacturers Ass'n, Inc. v. EPA*, —— F.2d ——, —— (D.C. Cir. No. 78-1896, decided August 3, 1979) (slip op. at 17).

Thus mindful of our restricted role, we turn to consider petitioners' claims. Petitioners posit three basic questions for decision. First, did the Administrator exceed his authority under the statute in promulgating the lead standards? Second, were key elements in the Administrator's analysis arbitrary or capricious? Third, do alleged procedural shortcomings in the lead standards rulemaking warrant a remand of the regulations to EPA?

---

[33] Thus in *Train v. Natural Resources Defense Council, Inc.*, 421 U.S. 60, 75 (1975), the Supreme Court, in upholding EPA's interpretation of a provision of the Clean Air Act despite the contrary views of a number of circuits, stated:

> Without going so far as to hold that the Agency's construction of the Act was the only one it permissibly could have adopted, we conclude that it was at the very least sufficiently reasonable that it should have been accepted by the reviewing courts.

V. Statutory Authority

The petitioners' first claim is that the Administrator exceeded his authority under the statute by promulgating a primary air quality standard for lead which is more stringent than is necessary to protect the public health because it is designed to protect the public against "subclinical" effects which are not harmful to health. According to petitioners, Congress only authorized the Administrator to set primary air quality standards that are aimed at protecting the public against health effects which are known to be *clearly harmful.* They argue that Congress so limited the Administrator's authority because it was concerned that excessively stringent air quality standards could cause massive economic dislocation.

In developing this argument St. Joe contends that EPA erred by refusing to consider the issues of economic and technological feasibility in setting the air quality standards for lead. St. Joe's claim that the Administrator should have considered these issues is based on the statutory provision directing him to allow an "adequate margin of safety" in setting primary air quality standards. In St. Joe's view, the Administrator must consider the economic impact of the proposed standard on industry and the technological feasibility of compliance by emission sources in determining the appropriate allowance for a margin of safety.[34] St. Joe argues that the Administrator abused his discretion by refusing to consider these factors in determining the appropriate margin of safety for the lead standards, and maintains that the

---

[34] *See* brief for petitioner St. Joe Minerals Corp. at 17-21. Other factors that should, in St. Joe's view, be considered are the severity of the associated health effects and the adequacy of the scientific base for determination of the health protective threshold level. *Id.*

lead air quality standards will have a disastrous economic impact on industrial sources of lead emissions.

This argument is totally without merit. St. Joe is unable to point to anything in either the language of the Act or its legislative history that offers any support for its claim that Congress, by specifying that the Administrator is to allow an "adequate margin of safety" in setting primary air quality standards, thereby required the Administrator to consider economic or technological feasibility. To the contrary, the statute and its legislative history make clear that economic considerations play no part in the promulgation of ambient air quality standards under Section 109.

Where Congress intended the Administrator to be concerned about economic and technological feasibility, it expressly so provided. For example, Section 111 of the Act, 42 U.S.C. § 7411, directs the Administrator to consider economic and technological feasibility in establishing standards of performance for new stationary sources of air pollution based on the best available control technology. *See Nat'l Asphalt Pavement Ass'n v. Train, supra,* 539 F.2d 775; S. Rep. No. 91-1196, 91st Cong., 2d Sess. 416 (1970).[35] In contrast, Section 109(b) speaks only of protecting the public health and welfare.[36] Nothing in its language suggests that the Administrator is

---

[35] *See also, e.g.,* § 110(e)(1), 42 U.S.C. § 7410(e)(1); § 113(d)(4)(c)(ii), 42 U.S.C. § 7413(d)(4)(c)(ii); § 202(a)(3)(C), 42 U.S.C. § 7521(a)(3)(C); § 231(b), 42 U.S.C. § 7571(b).

[36] Section 302(h), 42 U.S.C. § 7602(h), defines "welfare" to include "effects on economic values." This definition does not, however, include the cost of compliance with the air quality standards. It only refers to the economic costs of pollution. *Motor & Equipment Manufacturers Ass'n, Inc. v. EPA,* —— F.2d ——, —— (D.C. Cir. No. 78-1896, decided Aug. 3, 1979) (slip op. at 43).

to consider economic or technological feasibility in setting ambient air quality standards.[37]

The legislative history of the Act also shows the Administrator may not consider economic and technological feasibility in setting air quality standards; the absence of any provision requiring consideration of these factors was no accident; it was the result of a deliberate decision by Congress to subordinate such concerns to the achievement of health goals. Exasperated by the lack of significant progress toward dealing with the problem of air pollution under the Air Quality Act of 1967, 81 STAT. 485, and prior legislation, Congress abandoned the approach of offering suggestions and setting goals in favor of "taking a stick to the States in the form of the Clean Air Amendments of 1970 * * *." *Train v. Natural Resources Defense Council, Inc., supra*, 421 U.S. at 64; *see Union Electric Co. v. EPA*, 427 U.S. 246, 256-257 (1976).

---

[37] Other provisions of the Act closely related to § 109 confirm the view that the Administrator is not required or allowed to consider economic and technological feasibility in setting air quality standards. Section 108(a)(2), 42 U.S.C. § 7408(a)(2), which outlines the criteria on which the air quality standards are to be based, makes no mention of such factors. Similarly, § 110, 42 U.S.C. § 7410, provides that once ambient air quality standards have been promulgated, each state must prepare and submit an implementation plan outlining the measures to be taken to ensure that the standards are met. It is these state implementation plans which actually impose pollution control requirements and, consequently, if Congress had wanted the economics of pollution control considered, it would have so provided in § 110. While states may consider economic and technological feasibility in selecting the mix of control devices, they may do so only insofar as this does not interfere with meeting the strict deadlines for attainment of the standards. Section 110(a)(2), 42 U.S.C. § 7410(a)(2). *See Union Electric Co. v. EPA*, 427 U.S. 246, 257-258, 266 (1976). Moreover, the Administrator, in reviewing a state implementation plans, may not consider economic or technological feasibility. *Id.* at 265.

Congress was well aware that, together with Sections 108 and 110, Section 109 imposes requirements of a "technology-forcing" character. *Id.* at 257; *Train v. Natural Resources Defense Council, Inc., supra,* 421 U.S. at 91; *Ethyl Corp. v. EPA, supra,* 541 F.2d at 14. The Senate Report on the 1970 Amendments declared:

> The protection of public health—as required by the national ambient air quality standards * * *—will require major action throughout the Nation. Many facilities will require major investments in new technology and new processes. Some facilities will need altered operating procedures * * *. Some may be closed.
>
> * * * *
>
> In the Committee discussions, considerable concern was expressed regarding the use of the concept of technical feasibility as the basis of ambient air standards. The Committee determined that 1) the health of people is more important than the question of whether the early achievement of ambient air quality standards protective of health is technically feasible; and, 2) the growth of pollution load in many areas, even with application of available technology, would still be deleterious to public health.

The Report concluded:

> Therefore, the Committee determined that existing sources of pollutants either should meet the standard of the law or be closed down, and in addition that new sources should be controlled to the maximum extent possible to prevent atmospheric emissions.

S. Rep. No. 91-1196, *supra,* at 2-3. It is difficult to reconcile these statements of legislative intent with St. Joe's claim that Congress wanted the Administrator to consider economic and technological feasibility in setting air quality standards. The "technology-forcing" requirements of the Act "are expressly designed to force regulated sources to

develop pollution control devices that might at the time appear to be economically or technologically infeasible." *Union Electric Co. v. EPA*, *supra*, 427 U.S. at 257.

Furthermore, St. Joe's attempt to find a mandate for the Administrator to consider economic or technological feasibility in the Act's "adequate margin of safety" requirement is to no avail. The Senate Report explained the purpose of the margin of safety requirement:

> Margins of safety are essential to any health-related environmental standards if a reasonable degree of protection is to be provided against hazards which research has not yet identified.

S. Rep. No. 91-1196, *supra*, at 10. We are unable to discern here any congressional intent to require, or even permit, the Administrator to consider economic or technological factors in promulgating air quality standards. And when Congress directs an agency to consider only certain factors in reaching an administrative decision, the agency is not free to trespass beyond the bounds of its statutory authority by taking other factors into account. *American Overseas Airlines, Inc. v. CAB*, 254 F.2d 744, 748 (D.C. Cir. 1958). A policy choice such as this is one which only Congress, not the courts, and not EPA, can make. Indeed, the debates on the Act indicate that Congress was quite conscious of this fact. For example, Senator Muskie, one of the prime architects of the Act, in speaking about the automobile emission standards and the automobile industry, noted:

> * * * I think that we have an obligation to lay down the standards and requirements of this bill.
>
> I think that the industry has an obligation to try to meet them. If, in due course, it cannot, then it should come to Congress and share with the Congress—the representatives of the people—the need to modify the policy.

1 LEGISLATIVE HISTORY OF CLEAN AIR ACT AMENDMENTS OF 1970 at 232 (Senate Debate on S. 4358, Sept. 21, 1970) (hereinafter Legis. Hist.). *See also id.* at 236-240.[38] In the same manner, if there is a problem with the economic or technological feasibility of the lead standards, St. Joe, or any other party affected by the standards, must take its case to Congress, the only institution with the authority to remedy the problem.[39]

---

[38] Congress has in fact acted to change the requirements of the Act in particular instances. For example, the 1977 Amendments to the Act relaxed and extended the automobile emission standards. Section 202, 42 U.S.C. § 7521; 123 CONG. REC. S13702-S13704 (daily ed. Aug. 4, 1977); *id.* H8659-H8662. The lead industry was a beneficiary of such a change when Congress added the nonferrous smelter orders provision to the Act in the 1977 Amendments. Section 119, 42 U.S.C. § 7419. That section provides that the deadline for compliance with limitations necessary to meet the air quality standards for sulphur dioxide may, under certain conditions, be extended for up to 10 years.

[39] Indeed, at least some industry representatives have shown that they were aware of the fact that the Administrator may not consider economic or technological factors in setting air quality standards. At the time of the 1977 Amendments to the Act, industry spokesmen unsuccessfully attempted to persuade Congress to amend § 109 to require the Administrator to consider these factors. In a letter to Senator Muskie, a prime architect of the 1977 Amendments, Dow Chemical Company urged:

> *Recommendations for Change in the Law*
>
> In order to avoid the undesirable strangulation of reasonable economic development within major contributing sections of American society, we recommend that the Clean Air Act be amended to incorporate several concepts as follows:
>
> Revise section 109 * * * to include allowance for the consideration of social and economic factors in the definition of "health" and "welfare." * * *

Hearings before the Subcommittee on Environmental Pollution of the Committee on Environment and Public Works,

It may well be that underlying St. Joe's argument is its feeling that Congress could not or should not have intended this result, and that this court should supply relief by grafting a requirement of economic or technological feasibility onto the statute. The Supreme Court confronted a similar suggestion in the Tellico Dam case. *TVA v. Hill*, 437 U.S. 153 (1978). There TVA argued that the Endangered Species Act should not be construed to prevent operation of the dam since it had already been completed at a cost of approximately $100 million, Congress had appropriated funds for the dam even after the Act was passed, and the species at risk—the snail darter—was relatively unimportant and ways might ultimately be found to save it. The Court rejected the invitation to "view the * * * Act 'reasonably,' and hence shape a remedy that 'accords with some modicum of common sense and the public weal.'" *Id.* at 194. The Court pointed out:

> Our individual appraisal of the wisdom or unwisdom of a particular course consciously selected by the Congress is to be put aside in the process of interpreting a statute. Once the meaning of an enactment is discerned and its constitutionality determined, the judicial process comes to an end. We do not sit as a committee of review, nor are we vested with the power of veto. * * *

Id. at 194-195. Without suggesting that the Administrator's interpretation of the statute does not "accord[] with some modicum of common sense and the public weal," the Supreme Court's admonition reinforces our decision to reject St. Joe's invitation to construe the

---

United States Senate, 95th Cong., 1st Sess. Part 1 at 1085 (Committee Print 1977). Obviously if, as St. Joe claims, § 109 already required the Administrator to take such factors into consideration, Dow Chemical's proposed amendment would have been unnecessary.

statute as requiring the Administrator to consider economic and technological feasibility in promulgating air quality standards.

For its part, LIA maintains that its claim that the Administrator exceeded the bounds of his statutory authority does not depend on the supposition that he is required, or even permitted, to consider economic and technological feasibility in setting air quality standards. LIA contends that, instead, its argument is based on the fact that Congress itself was concerned about the question of the economic feasibility of compliance with air quality standards, a concern which was reflected in the statute it enacted. According to LIA, Congress was mindful of the possibility that air quality standards which are too stringent could cause severe economic dislocation. For this reason it only granted the Administrator authority to adopt air quality standards which are "designed to protect the public from adverse health effects that are clearly harmful[.]"[40] LIA finds support for its interpretation of congressional intent in various portions of the legislative history of the Act. For example, it notes that the Senate Report on the 1970 legislation states that EPA "would be required to set a national *minimum* standard of air quality," S. Rep. No. 91-1196, *supra*, at 10 (emphasis added), and that Senator Muskie pointed out during the floor debates that "air quality standards which will protect the public must be set as *minimum standards* * * *." 1 Legis. Hist., *supra*, at 125 (emphasis added).[41] LIA then argues that the Adminis-

---

[40] Brief for petitioner LIA at 17-18.

[41] LIA also argues that the legislative history of the 1977 Amendments provides further support for its interpretation. It points out that the House Report on the Amendments stated:

> Some have suggested that since the standards are to protect against all known or anticipated effects and since

trator based the lead air quality standards on protecting children from "subclinical" effects of lead exposure which have not been shown to be harmful to health, that in so doing the Administrator ignored the clear limitation that Congress imposed on his standard-setting powers, and that the Administrator's action will in fact cause the very result that Congress was so concerned about avoiding.

LIA's argument appears to touch on two issues. The first concerns the type of health effects on which the Administrator may base air quality standards, *i.e.*, the point at which the Administrator's regulatory authority

---

> no safe thresholds can be established, the ambient standards should [b]e set at zero or background levels. Obviously, this no-risk philosophy ignores all economic and social consequences and is impractical. This is particularly true in light of the legal requirement for mandatory attainment of the national primary standards within 3 years.

H.R. Rep. No. 95-294, 95th Cong., 1st Sess. 127 (1977). LIA further notes that Senator Muskie remarked during the floor debates on the 1977 Amendments:

> In the first place, the national primary and secondary standards were set for dirty air areas as the minimum necessary and the minimum reasonably attainable in the dirty air areas, in order to put them up to minimal health standards. They are not ultimate; they are not maximum; they are minimal. And, if I may highlight this, testimony on the health question over the last 7 years over and over again has made the point that there is no such thing as a threshold for health effects. *Even at the national primary standard level, which is the health standard, there are health effects that are not protected against.*

123 CONG. REC. S9423 (daily ed. June 10, 1977) (*quoted in* brief for petitioner LIA, LIA's emphasis). All these statements, in LIA's view, demonstrate that Congress limited the Administrator's standard-setting powers to protecting against effects which are *clearly harmful to health.*

may be exercised. This issue, as LIA suggests, does concern the limits that the Act, and its legislative history, may place on the Administrator's authority. The second issue appears to be more in the nature of an evidentiary question: whether or not the evidence in the record substantiates the Administrator's claim that the health effects on which the standards were based do in fact satisfy the requirements of the Act. Although these two issues are closely related, they are conceptually distinct, and they are best examined separately.

Section 109(b) does not specify precisely what Congress had in mind when it directed the Administrator to prescribe air quality standards that are "requisite to protect the public health." The legislative history of the Act does, however, provide some guidance. The Senate Report explains that the goal of the air quality standards must be to ensure that the public is protected from "adverse health effects." S. Rep. No. 91-1196, *supra*, at 10. And the report is particularly careful to note that especially sensitive persons such as asthmatics and emphysematics are included within the group that must be protected. It is on the interpretation of the phrase "adverse health effects" that the disagreement between LIA and EPA about the limits of the Administrator's statutory authority appears to be based. LIA argues that the legislative history of the Act indicates that Congress only intended to protect the public against effects which are known to be *clearly harmful* to health,[42] maintaining that this limitation on the Administrator's statutory authority is necessary to ensure that the standards are not set at a level which is more stringent than Congress contemplated. The Administrator, on the other hand, agrees

---

[42] LIA notes that in *Ethyl Corp. v. EPA*, *supra* note 29, 541 F.2d at 14 n.20, this court suggested that the term "adverse effect," when used without the modifier "known or anticipated," refers to "known adverse effects or actual harm."

that primary air quality standards must be based on protecting the public from "adverse health effects," but argues that the meaning LIA assigns to that phrase is too limited. In particular, the Administrator contends that LIA's interpretation is inconsistent with the precautionary nature of the statute, and will frustrate Congress' intent in requiring promulgation of air quality standards.

The Administrator begins by pointing out that the Act's stated goal is "to protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare and the productive capacity of its population[.]" Section 101(b)(1), 42 U.S.C. § 7401(b)(1). This goal was reaffirmed in the 1977 Amendments. For example, the House Report accompanying the Amendments states that one of its purposes is "[t]o emphasize the preventive or precautionary nature of the act, i.e., to assure that regulatory action can effectively prevent harm before it occurs; to emphasize the predominant value of protection of public health[.]" H.R. Rep. No. 95-294, 95th Cong., 1st Sess. 49 (1977). The Administrator notes that protecting the public from harmful effects requires decisions about exactly what these harms are, a task Congress left to his judgment. He notes that the task of making these decisions is complicated by the absence of any clear thresholds above which there are adverse effects and below which there are none. Rather, as scientific knowledge expands and analytical techniques are improved, new information is uncovered which indicates that pollution levels that were once considered harmless are not in fact harmless. Congress, the Administrator argues, was conscious of this problem, and left these decisions to his judgment partly for this reason.[43]

---

[43] Section 109(b), 42 U.S.C. § 7409(b), specifically states that the Administrator is to use his judgment in determining what air quality standards are necessary to protect the public

In such situations the perspective that is brought to bear on the problem plays a crucial role in determining what decisions are made. Because it realized this, Congress, the Administrator maintains, directed him to err on the

---

health, a task which requires him to make factual determinations as well as policy judgments.

The Administrator notes that the issue of the uncertainty that surrounds attempts to set air quality standards which protect the public health featured prominently in the discussion about the 1977 Amendments. For example, noting that the primary standards are based on the assumption that there is a discoverable no-effects threshold, the House Report on the Amendments observed:

> However, in no case is there evidence that the threshold levels have a clear physiological meaning, in the sense that there are genuine adverse health effects at and above some level of pollution, but no effects at all below that level. On the contrary, evidence indicates that the amount of health damage varies with the upward and downward variations in the concentration of the pollutant, with no sharp lower limit.

H.R. Rep. No. 95-294, *supra* note 41, at 110 (*quoting* 1974 National Academy of Sciences Report at 17). *See* H.R. Rep. No. 95-294, *supra*, at 105-127. And during the Senate debate on the Amendments Senator Muskie summarized the problems the Administrator faces in attempting to set air quality standards:

> * * * I wish it were possible for the Administrator to set national primary and secondary standards that fully implement the statutory language * * *.
>
> * * * The fact is, as testimony and documents disclose, the standards do not fully protect in accordance with the statutory language which gives the Administrator authority to provide for additional protection. He has had to make a pragmatic judgment in the face of the fact that he found there is no threshold on health effects, which makes it very difficult then to apply absolute health protection, and he has not been able to do that.

123 CONG. REC. S9426 (daily ed. June 10, 1977).

side of caution in making these judgments. First, Congress made it abundantly clear that considerations of economic or technological feasibility are to be subordinated to the goal of protecting the public health by prohibiting any consideration of such factors. Second, it specified that the air quality standards must also protect individuals who are particularly sensitive to the effects of pollution. Third, it required that the standards be set at a level at which there is "an absence of adverse effect" on these sensitive individuals. Finally, it specifically directed the Administrator to allow an adequate margin of safety in setting primary air quality standards in order to provide some protection against effects that research has not yet uncovered. The Administrator contends that these indicia of congressional intent, the precautionary nature of the statutory mandate to protect the public health, the broad discretion Congress gave him to decide what effects to protect against, and the uncertainty that must be part of any attempt to determine the health effects of air pollution, are all extremely difficult to reconcile with LIA's suggestion that he can only set standards which are designed to protect against effects which are *known to be clearly harmful to health.*

We agree that LIA's interpretation of the statute is at odds with Congress' directives to the Administrator. As a preliminary matter, though it denies this, LIA does at times seem to be arguing, along with St. Joe, that the Administrator should have considered economic and technological feasibility in setting the standards,[44] a claim that must be rejected for reasons we have already stated.[45] Be that as it may, it is not immediately clear why LIA expects this court to impose limits on the Administrator's authority which, so far as we can tell, Con-

---

[44] *See, e.g.*, brief for petitioner LIA at 13, 16-17, 29-30.

[45] *See* —— F.2d at ——-—— (pp. 32-38) *supra.*

gress did not. The Senate Report explains that the Administrator is to set standards which ensure that there is "an absence of adverse effects." The Administrator maintains that the lead standards are designed to do just that, a claim we will examine in due course. But LIA would require a further showing—that the effects on which the standards were based are *clearly* harmful or *clearly* adverse. We cannot, however, find the source of this further restriction that LIA would impose on the Administrator's authority.[46] It may be that it reflects LIA's view that the Administrator must show that there is a "medical consensus that [the effects on which the standards were based] are harmful * * *."[47] If so, LIA is seriously mistaken. This court has previously noted that some uncertainty about the health effects of air pollution is inevitable.[48] And we pointed out that

---

[46] Perhaps a charitable interpretation of LIA's position is that it does not really question the Administrator's claim that the statutory scheme only requires him to show that the effects on which the standards are based are "adverse to health." However, LIA does challenge the Administrator's conclusion that the particular effects on which the lead standards were based are in fact adverse to health. If so, LIA's attack is not directed at the Administrator's statutory authority. Rather, it is aimed at the evidentiary support for the Administrator's conclusion. As we have said, we will examine this question in due course. We note, however, that LIA presents its claim as an attack on the Administrator's authority under the Act, and at this point we are treating it as such.

[47] Brief for petitioner LIA at 20.

[48] In *Ethyl Corp. v. EPA*, *supra* note 29, 541 F.2d at 24-25, we pointed out:

> Questions involving the environment are particularly prone to uncertainty. Technological man has altered his world in ways never before experienced or anticipated. The health effects of such alterations are often unknown, sometimes unknowable. While a concerned Congress has passed legislation providing for protection of the public

"[a]waiting certainty will often allow for only reactive, not preventive regulat[ory action]." *Ethyl Corp. v. EPA*, *supra*, 541 F.2d at 25. Congress apparently shares this view; it specifically directed the Administrator to allow an adequate margin of safety to protect against effects which have not yet been uncovered by research and effects whose medical significance is a matter of disagreement.[49] This court has previously acknowledged the role

---

health against gross environmental modifications, the regulators entrusted with the enforcement of such laws have not thereby been endowed with a prescience that removes all doubt from their decisionmaking. Rather, speculation, conflicts in evidence, and theoretical extrapolation typify their every action. How else can they act, given a mandate to protect the public health but only a slight or nonexistent data base from which to draw? * * * Sometimes, of course, relatively certain proof of danger or harm from such modifications can readily be found. But, more commonly, "reasonable medical concerns" and theory long precede certainty. Yet the statutes—and common sense—demand regulatory action to prevent harm, even if the regulator is less than certain that harm is otherwise inevitable.

Undoubtedly, certainty is the scientific ideal—to the extent that even science can be certain of its truth. But certainty in the complexities of environmental medicine may be achievable only after the fact, when scientists have the opportunity for leisurely and isolated scrutiny of an entire mechanism. * * *

(Footnotes omitted.)

[49] In *Environmental Defense Fund v. EPA*, 598 F.2d 62, 81 (1978), we discussed the significance of the margin of safety requirement, pointing out that "the use of the term * * * was * * * meant by Congress to take into account and compensate for uncertainties and lack of precise predictions in the area of forecasting the effects of toxic pollutants * * *." *Quoting* Hall, *The Control of Toxic Pollutants Under the Federal Water Pollution Control Act Amendments of 1972*, 63 IOWA L. REV. 609, 629-630 (1979).

of the margin of safety requirement. In *Environmental Defense Fund v. EPA*, 598 F.2d 62, 81 (1978), we pointed out that "[i]f administrative responsibility to protect against unknown dangers presents a difficult task, indeed, a veritable paradox—calling as it does for knowledge of that which is unknown—then, the term 'margin of safety' is Congress's directive that means be found to carry out the task and to reconcile the paradox." Moreover, it is significant that Congress has recently acknowledged that more often than not the "margins of safety" that are incorporated into air quality standards turn out to be very modest or nonexistent, as new information reveals adverse health effects at pollution levels once thought to be harmless. *See* H.R. Rep. No. 95-294, *supra*, at 103-117. Congress' directive to the Administrator to allow an "adequate margin of safety" alone plainly refutes any suggestion that the Administrator is only authorized to set primary air quality standards which are designed to protect against health effects that are known to be clearly harmful.

Furthermore, we agree with the Administrator that requiring EPA to wait until it can conclusively demonstrate that a particular effect is adverse to health before it acts is inconsistent with both the Act's precautionary and preventive orientation and the nature of the Administrator's statutory responsibilities. Congress provided that the Administrator is to use his judgment in setting air quality standards precisely to permit him to act in the face of uncertainty.[50] And as we read the statutory

---

[50] The House Report on the 1977 Amendments discussed the significance of the provision that the Administrator is to use his judgment in making the decisions required under the Act. It explained that the purpose is:

> To reflect awareness of the uncertainties and limitations in the data which will be available to the Administrator in the foreseeable future to enable him to execute his rulemaking duties under this act, because of the limi-

provisions and the legislative history, Congress directed the Administrator to err on the side of caution in making the necessary decisions. We see no reason why this court should put a gloss on Congress' scheme by requiring the Administrator to show that there is a medical consensus that the effects on which the lead standards were based are "*clearly harmful to health.*" All that is required by the statutory scheme is evidence in the record which substantiates his conclusions about the health effects on which the standards were based.[51] Accordingly, we reject LIA's

---

tations on research resources and the fact that decision-making about the risks to public health from air pollution falls on "the frontiers of scientific and medical knowledge"; to provide for adequate judicial review of the reasonableness of the Administrator's judgment in assessing risks, while restraining the courts from attempting to act "as the equivalent of a combined Ph.D. in chemistry, biology, and statistics" or from applying a standard of review which is appropriate only to review of adjudications or formal fact finding.

H.R. Rep. No. 95-294, *supra* note 41, at 50. Although this discussion specifically relates to the use of the phrase "in [the Administrator's] judgment" in sections of the Act other than § 109(b), the discussion undoubtedly also illuminates Congress' intentions with regard to its use in § 109(b).

[51] We find nothing in the portions of the legislative history cited by LIA, *see* text and note at note 41 *supra*, that supports the claim that Congress limited the Administrator's authority in the manner LIA suggests. The passage in the Senate Report which describes the national air quality standards as "minimum standards" merely refers to the fact that the states are free to adopt air quality standards which are more stringent than the national standards. S. Rep. No. 91-1196, 91st Cong., 2d Sess. 10 (1970). *See* 42 U.S.C. § 7416. Moreover, it is difficult to see how the suggestion that the national standards are "minimum standards" implies that the Administrator must wait until there is a consensus among medical experts that certain effects are clearly adverse to health before he can base air quality standards on these effects. And the suggestions by Senator Muskie and the 1977 House Re-

claim that the Administrator exceeded his statutory authority and turn to LIA's challenge to the evidentiary basis for the Administrator's decisions.

---

port that the air quality standards should not be set at zero or background levels by no means imply that the standards may only be based on effects which *all* the experts agree are clearly harmful to health. The Administrator has not suggested that he has the authority to protect against all effects of air pollution, whether or not they are adverse to health. Indeed, he specifically noted that the health effects of lead exposure begin at blood lead levels of 15-20 ug Pb/dl, and concluded that these effects are not significant enough to be regarded as adverse to health until blood lead concentrations reach a level of 30 ug Pb/dl. 43 FED. REG. 46253, JA 2955. As should be evident from the numerous references we have made to it, the House Report on the 1977 Amendments provides support for the Administrator's interpretation of the Act, not LIA's.

LIA's reliance on our statement in the *Ethyl* case that the term "adverse effects" refers to "known adverse effects or actual harm," 541 F.2d at 14 n.20, is misplaced. First, this statement does not suggest, as does LIA, that "adverse effects" only encompasses effects that are *clearly* adverse or *clearly* harmful. Second, the statement was made in the context of our discussion of the threshold showing that was required to justify listing of a pollutant under then § 108(a)(1)(A), 42 U.S.C. § 1857c-3(a)(1)(A) (1976). We pointed out that the Administrator was required to show that the pollutant causes actual harm before it could be listed for regulation. But we also made it clear that while the threshold decision to regulate under then § 108 was not precautionary, once the decision to regulate was made § 109 required that the standards promulgated be preventive in nature. *See* 541 F.2d at 14-15. The 1977 Amendments changed § 108 by making the threshold decision to regulate precautionary in nature. *See* 42 U.S.C. § 7408(a)(1)(A) (Supp. I 1977); H.R. Rep. No. 95-294, *supra* note 41, at 49-51.

Finally, even if we did disagree with the Administrator's interpretation of the term "adverse effects," we would nevertheless be constrained to accept it since it is reasonable and consistent with the goals of the statute. *See Train v. Natural Resources Defense Council, Inc.*, *supra*, note 33, 421 U.S. at 75, 87; *Ethyl Corp. v. EPA*, *supra* note 29, 541 F.2d at 12 n.16.

VI. Health Basis for the Lead Standards

LIA does not question a number of the steps in the Administrator's analysis. It does not disagree with his selection of children between the ages of one and five years as the target population, or the decision to set a standard that would keep 99.5 percent of the children below the maximum safe individual blood lead level. In addition, LIA does not challenge the Administrator's suggestion that the standards should be based on an assumption that non-air sources contribute 12 ug Pb/dl to blood lead levels. LIA does, however, challenge other key elements in the Administrator's analysis.

A. *Maximum Safe Individual Blood Lead Level*

LIA attacks the Administrator's determination that 30 ug Pb dl should be considered the maximum safe individual blood lead level for children, maintaining that there is no evidence in the record indicating that children suffer any health effects that can be considered adverse at this blood lead level. As previously noted,[52] the Administrator's selection was based on his finding that EP elevation at 30 ug Pb/dl is the first adverse health effect of lead exposure, and his determination that a maximum safe individual blood lead level of 30 ug Pb/dl will allow an adequate margin of safety in protecting children against the more serious effects of lead exposure—anemia, symptoms of which appear at blood lead levels of 40 ug Pb/dl and central nervous system deficits which begin to occur at blood lead levels of 50 ug Pb/dl.

LIA challenges each of these findings. First, it contends that nothing in the record supports the suggestion that EP elevation at 30 ug Pb/dl is harmful to health, arguing that EP elevation is a mere "subclinical effect"—a biological response to lead exposure—which is without

---

[52] *See* —— F.2d at —— (pp. 22-23) *supra*.

health significance, and noting that a number of its experts brought this matter to EPA's attention in their comments on the proposed standards.[53] In LIA's view, the Administrator did not explain precisely how impairment of heme synthesis at blood lead levels of 30 ug Pb/dl adversely affects the health of children.[54] Second, LIA challenges the Administrator's determination that a maximum safe individual blood lead level of 30 ug Pb/dl is justified by the need to allow an adequate margin of safety in protecting children against anemia and central nervous system deficits. It maintains that the evidence in the record does not support the Administrator's conclusion that the blood lead threshold for the symptoms of anemia in children is 40 ug Pb/dl. LIA claims that this error was brought to the Administrator's attention by comments on the proposed standard, but that he failed to respond to these comments, thereby violating the statutory provision requiring him to respond to "significant comments, criticisms, and new data submitted * * * during the comment period."[55] Third, LIA contends that the preamble to the final regulations does not state the basis for the Administrator's finding that central nervous system deficits occur in children at blood lead levels of 50 ug Pb/dl, thereby precluding this court from being able to test the soundness of this determination. Finally, LIA argues that even if it were to concede that EPA's conclusions about the blood lead thresholds for anemia and

---

[53] LIA cites comments and statements by Chisolm (JA 1773-1774); McCabe (JA 1756, 1760-1761); McNeil (JA 1790-1794); Sachs (JA 2149-2150); Jandl (JA 2388-2390, 2393, 2399); Panke (JA 2344).

[54] In LIA's view, the first clearly adverse effect of lead exposure is anemia which occurs in children at blood lead levels well in excess of 40 ug Pb/dl. *See* brief for petitioner LIA at 24-25.

[55] 42 U.S.C. § 7607(d)(6)(B).

central nervous system deficits are correct, there is still no explanation of why the Administrator concluded that a maximum individual safe blood lead level of 30 ug Pb/dl—rather than 35 ug Pb/dl, for example—is necessary to provide an adequate margin of safety against these effects.

Our review of the record persuades us that there is adequate support for each of the Administrator's conclusions about the health effects of lead exposure and, consequently, that LIA's challenges to the evidentiary support for these findings must be rejected. Under the statutory scheme enacted by Congress, the Criteria Document prepared with respect to each pollutant is to provide the scientific basis for promulgation of air quality standards for the pollutant. We have already noted that the Lead Criteria Document was the product of a process that allowed the rigorous scientific and public review that are essential to the preparation of a document "accurately reflect[ing] the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects [of lead exposure] on [the] public health * * *."[56] In our view, the Criteria Document provides ample support for the Administrator's findings.

The Criteria Document concluded that EP elevation, which begins in children at blood lead levels of 15-20 ug Pb/dl, is one of the more significant effects of low level lead exposure because it indicates that lead has already begun to affect basic biological functions in the body. We have already examined in some detail the findings that led the Criteria Document to the conclusion that EP elevation is an indication of a physiological impairment which affects human health.[57] Briefly stated, it con-

---

[56] 42 U.S.C. § 7408(a)(2). *See* —— F.2d at —— (pp. 10-11) *supra* and note 7 *supra*.

[57] *See* —— F.2d at —— (pp. 11-13) *supra*.

cluded that EP elevation indicates an impairment of the functioning of the mitochondria[58]; that EP elevation indicates that lead has begun to affect the process of heme synthesis; that EP elevation may indicate a reduction in any reserve capacity there might be in the heme synthesis system; and that lead's impairment of heme synthesis in the blood suggests that lead may also interfere with production of heme proteins in other organ systems. Relying on the Criteria Document's discussion, as well as other evidence in the record, the Administrator made a judgment that for purposes of setting air quality standards for lead, EP elevation at 30 ug Pb/dl must be considered the first adverse effect on the health of children, and he determined that the maximum safe individual blood lead level should be no higher than 30 ug Pb/dl.

The Administrator's judgment echoes the consensus of a group of clinicians who, in 1975, participated in preparation of a statement issued by the Center For Disease Control and endorsed by the American Academy of Pediatrics. These experts agreed that EP elevation "should be used as an indicator of a significant and worrisome body burden of lead." CD 11-14, JA 1236. Moreover, the Center For Disease Control uses EP elevation at 30 ug Pb/dl as the cutoff point for detection of lead poisoning in children in its screening programs,[59]

---

[58] LIA disputes this conclusion, arguing that the Administrator ignored comments which challenged the basis for the finding. Brief for petitioner LIA at 34. We do not agree. The Administrator simply decided, in the face of contrary evidence, both in the Criteria Document, CD 11-8 - 11-14, 13-5, JA 1230-1236, 1335, and elsewhere in the record, JA 2607-2611 (Piomelli); JA 2612-2616 (Silbergeld); JA 1563-1564 (Landrigan), that EP elevation indicates an impairment of mitochondrial function. 43 FED. REG. 46249, JA 2951.

[59] CENTER FOR DISEASE CONTROL, INCREASED LEAD ABSORPTION AND LEAD POISONING IN YOUNG CHILDREN (1975). JA 1401-1409.

a factor that influenced the Administrator's decision. 43 FED. REG. 46253, JA 2955. The Administrator's reliance on this was, in our view, entirely appropriate. While the Center has indicated that children with a blood lead concentration of 30 ug Pb/dl have a lead problem,[60] it is also significant that the Center's screening program has much the same preventive and precautionary approach that Congress directed the Administrator to apply to the task of setting air quality standards designed to protect the public health.[61] Further support for the Administrator's decisions is provided by the testimony of various medical and other scientific experts who participated in the lead standards rulemaking. These experts endorsed the Administrator's (and Criteria Document's) conclusions about the effects of low level lead exposures, and agreed with his assessment of the health significance of these effects.[62] The Administrator's decision is, of course, precisely the sort of issue that Congress specifically left to

---

[60] Dr. Landrigan, testifying on behalf of the Center at the hearing on the proposed standards, stated that EP elevation at 30 ug Pb/dl is used to

> indicate the children in a screening program who have already absorbed too much lead from their environment, who already have manifested abnormalities in the red cell enzyme systems * * *, and who may already possibly at least have subclinical alteration in the functioning of their central and peripheral nervous systems.

JA 1565-1566.

[61] Indeed, whereas the Center's screening program has the option of resorting to individual medical intervention to protect the health of the children affected, the Administrator must rely solely on the air quality standards to fulfill his statutory responsibility to protect the public health.

[62] *See* JA 2168-2169 (Needleman); JA 2499-2508, 2607-2610, 1608-1610 (Piomelli); JA 2581-2582 (Needleman and Piomelli); JA 2612-2614 (Silbergeld); JA 1563-1564, 2156-2159 (Landrigan).

his judgment, and where there is evidence in the record which supports these judgments, this court is not at liberty to substitute its judgment for the Administrator's. In this instance the Administrator has acted properly under the terms of the statute. He has explained his factual findings and policy judgments, and there is an adequate basis in the record for these decisions. No more is required of him.

LIA's challenge to the Administrator's findings concerning the health significance of EP elevation also stresses that this phenomenon is only a "subclinical" effect. But the clinical/subclinical distinction has little to do with the question whether a particular effect is properly viewed as adverse to health. Rather, the distinction pertains to the means through which the particular effect may be detected: observation or physical examination in the case of clinical effects, and laboratory tests in the case of subclinical effects.[63] Thus describing a particular effect as a "subclinical" effect in no way implies that it is improper to consider it adverse to health.[64] While EP elevation may not be readily identifiable as a sign of disease, the Administrator properly concluded that it indicates a lead-related interference with basic biological functions. Expert medical testimony in the record confirms that the modern trend in preventive medicine is to detect health problems in their "subclinical" stages, and thereupon to take corrective action.[65] Moreover, as we have already noted, the Center For Disease Control

---

[63] *See* note 11 *supra*.

[64] The Criteria Document suggests that death from lead poisoning may in fact occur without any prior clinical symptoms. CD 13-4, JA 1334.

[65] *See* JA 2608 (Piomelli); JA 2612 (Silbergeld); JA 2168-2169 (Needleman). Examples given include the use of abnormalities of the electrical current of the heart to detect heart problems, liver chemistry profiles to detect liver ailments, and

uses the same "subclinical" effect as the key indicator of the need for medical intervention in its lead poisoning screening program. The accepted use of this "subclinical" effect to determine the need for medical observation or intervention properly influenced the Administrator's decision.[66] Thus the fact that the effects the Administrator relied on in setting the lead standards are "subclinical" does not detract from their significance for human health, or make them an improper basis for setting air quality standards.

We also reject LIA's claim that the evidence in the record does not support the Administrator's determination that the blood lead threshold for symptoms of anemia in children is 40 ug Pb/dl. According to the Criteria Document, the onset of anemia is marked by a decline in the level of hemoglobin per unit of blood, CD 13-4, JA 1334. And the Criteria Document states that "[r]eports on children indicate that statistically significant decreases in hemoglobin levels begin to appear at a blood lead level of 40 ug [Pb]/dl or somewhat below." *Id.* At another point the Criteria Document explains, "In children, a threshold blood lead level for production of * * * symptoms of anemia is approximately 40 ug Pb/dl * * *." CD 1-6, JA 1110. *See id.* 11-13, JA 1235; JA 2583-2585 (Needleman and Piomelli). The Criteria Document's con-

---

changes in blood chemistry to detect a variety of health problems, including undue lead exposure. JA 2808 (Piomelli). In an article one of LIA's experts expressed approval for the approach of trying to detect lead poisoning in the "subclinical" stage and taking preventive action based on these effects. *See* JA 858-860 (Chisolm).

[66] A number of LIA's experts testified that they agree that the Center's use of EP elevation at 30 ug Pb/dl as the cutoff point in screening children for lead poisoning is sound preventive practice. *See* JA 1775 (Chisolm); JA 1766 (McCabe).

clusions were reached after a review of various studies that have examined the subject, and we cannot, in light of these findings, say that the Administrator's decision about the threshold blood lead level for the symptoms of anemia in children does not have an adequate basis in the record.[67]

Finally, our examination of the record also reveals ample support for the Administrator's determination that lead-induced central nervous system deficits begin to occur in children at blood lead levels of 50 ug Pb/dl. The central nervous system damage about which the Administrator was concerned was not the severe brain damage that can occur at relatively high levels of lead exposure—80-100 ug Pb/dl.[68] Rather, his focus was on more subtle and largely irreversible neurological and behavioral impairment that has been detected in children at lower blood lead levels, 43 FED. REG. 46253, JA

---

[67] Two of LIA's experts point out that a World Health Organization Report, "Environmental Health Criteria for Lead," also lists (to be sure, incorrectly in the view of these experts) the blood lead threshold for anemia at 40 ug Pb/dl. JA 2096 (Chisolm); JA 2087 (McCabe).

Petitioners and a number of their experts do not disagree with the Criteria Document's statement that a statistically significant decline in hemoglobin levels begins to occur in children at blood lead levels of 40 ug Pb/dl. *See* JA 1831, 2368 (LIA); JA 2178 (St. Joe); JA 2096 (Chisolm); JA 1760 (McCabe). Their disagreement with the Administrator's conclusion appears to center around the questions whether the statistically significant decline in hemoglobin levels at 40 ug Pb/dl is adverse to health, and whether this decline is a signal indicating the onset of anemia. *See* reply brief for petitioner LIA at 18.

[68] *See* —— F.2d at —— (pp. 13-14) *supra*.

2955.[69] The Criteria Document candidly admitted that "[t]he literature on this subject is somewhat limited and controversial," but it was nevertheless able to conclude that "certain statements [can] be made about the possible hazard of low to moderate lead exposure levels." CD 11-18, JA 1240. The conclusion it reached, after a detailed review of various studies that have examined the subject, was that:

> [The] evidence tends to confirm that some type of neural damage does exist in asymptomatic children, and not necessarily only at very high levels of blood lead. The body of studies on low- or moderate-level lead effects on neurobehavioral functions * * * present overall a rather impressive array of data pointing to that conclusion. Several well-controlled studies have found effects that are clearly statistically significant, whereas others have found nonsignificant but borderline effects. Even some studies reporting generally nonsignificant findings at times contain data confirming statistically significant effects, which the authors attribute to various extraneous factors. * * *

CD 11-26, JA 1248. The Criteria Document reported that the blood lead levels associated with these neurobehavioral deficits are 50-60 ug Pb/dl. *Id.* These conclusions were endorsed by several of the experts who participated in the lead standards rulemaking proceedings, including one of LIA's experts.[70] Some of these experts even suggested that these effects may occur at blood lead levels lower than the levels indicated by the Criteria Docu-

---

[69] The manifestations of these impairments include diminished capacity to think, reason, and control behavior, and emotional instability. *See* CD 11-18 - 11-28, JA 1240-1248.

[70] *See* JA 365-368 (NRDC); JA 976-981, 2612-2613 (Silbergeld); JA 853-855, 1564-1565 (Landrigan); JA 1621-1626 (Needleman); JA 2586-2588 (Needleman and Piomelli); JA 454 (David); JA 858-860 (Chisolm, LIA).

ment.[71] Contrary to LIA's suggestion, the evidence in the Criteria Document and the testimony of the experts provides an adequate basis for this court to undertake a review of the Administrator's findings concerning these effects. Accordingly, we reject LIA's challenge to the Administrator's conclusion that central nervous system deficits begin to occur in children at blood lead levels of 50 ug Pb/dl.

Our conclusion that there is ample support for the Administrator's determination that EP elevation at 30 ug Pb/dl is the first adverse health effect that children experience as a result of lead exposure is, of course, sufficient to sustain his selection of 30 ug Pb/dl as the maximum safe individual blood lead level. Given this, we cannot say that his further determination that a maximum safe individual blood lead level of 30 ug Pb/dl would in addition provide protection against the more serious adverse health effects of lead exposure was irrational.

To be sure, the Administrator's conclusions were not unchallenged; both LIA and the Administrator are able to point to an impressive array of experts supporting each of their respective positions.[72] However, disagreement among the experts is inevitable when the issues involved are at the "very frontiers of scientific knowledge," and such disagreement does not preclude us from finding that the Administrator's decisions are adequately supported by the evidence in the record. It may be that LIA expects this court to conclude that LIA's experts are right, and the experts whose testimony supports the Administrator are wrong.[73] If so, LIA has seriously misconceived our

---

[71] *See* JA 853-855, 1564-1565 (Landrigan); JA 365-368 (NRDC).

[72] *Compare* citations in note 53 *supra with* citations in notes 62 and 70 *supra*.

[73] *See, e.g.*, brief for petitioner LIA at 8 n.7, 12; reply brief for petitioner LIA at 4, 23.

role as a reviewing court. It is not our function to resolve disagreement among the experts or to judge the merits of competing expert views. *AFL-CIO v. Marshall*, —— F.2d ——, —— & n.66 (D.C. Cir. No. 78-1562, decided October 24, 1979) (slip op. at 26-27 & n.66); *cf. Hercules Inc. v. EPA*, 598 F.2d 91, 115 (D.C. Cir. 1978) ("[c]hoice among scientific test data is precisely the type of judgment that must be made by EPA, not this court"). Our task is the limited one of ascertaining that the choices made by the Administrator were reasonable and supported by the record. *Ethyl Corp. v. EPA*, *supra*, 541 F.2d at 35-36. That the evidence in the record may also support other conclusions, even those that are inconsistent with the Administrator's,[74] does not prevent us from concluding that his decisions were rational and supported by the record. *AFL-CIO v. Marshall*, *supra*, —— F.2d at —— n.66, slip op. at 27 n.66; *Environmental Defense Fund, Inc. v. EPA*, 510 F.2d 1292, 1298 (D.C. Cir. 1975); *accord, Bayside Enterprises, Inc. v. NLRB*, 425 U.S. 248, 302 (1976). *Cf. Universal Camera Corp. v. NLRB*, 340 U.S. 474, 488 (1951) ("a court may [not] displace the [agency's] choice between two fairly conflicting views, even though the court would justifiably have made a different choice had the matter been before it *de novo*").

Having determined that we must uphold the Administrator's decisions concerning the health effects that are the basis for the lead standards, we turn to petitioners' other challenges to the Administrator's analysis.

B. *Margin of Safety*

Both LIA and St. Joe argue that the Administrator erred by including multiple allowances for margins of safety in his calculation of the lead standards. Petition-

---

[74] We, of course, intimate no views about whether the evidence in the record in these cases supports conclusions that are inconsistent with the Administrator's.

ers note that the statute directs the Administrator to allow an "adequate margin of safety" in setting primary air quality standards, and they maintain that as a matter of statutory construction the Administrator may not interpret "margin" of safety to mean "margins" of safety. In petitioners' view, the Administrator in fact did just this insofar as he made allowances for margins of safety at several points in his analysis. They argue that margin of safety allowances were reflected in the choice of the maximum safe individual blood lead level for children, in the decision to place 99.5 percent of the target population group below that blood lead level, in the selection of an air lead/blood lead ratio of 1:2, and in the Administrator's estimate of the contribution to blood lead levels that should be attributed to non-air sources.[75] The net result of these multiple allowances for margins of safety, petitioners contend, was a standard far more stringent than is necessary to protect the public health. St. Joe suggests that EPA should have adopted an approach which required decisions on:

> 1) The maximum level of lead in air which is protective of health; *i.e.*, a threshold beyond which the public health is not protected; and
>
> 2) An adequate margin of safety by which the level which is protective of health must be reduced.[76]

EPA responds by maintaining that allowances for a margin of safety were made only at two points in its analysis: in the selection of a maximum safe individual blood lead level of 30 ug Pb/dl and in the decision to set

---

[75] Petitioners also contend that the Administrator's decision not to exclude non-respirable particles from the lead standards, *see* text and notes at notes 95-107 *infra*, provides yet another margin of safety because it overestimates the contribution to blood lead from air sources.

[76] Brief for petitioner St. Joe at 14.

a standard designed to keep 99.5 percent of the target population below that blood lead level. It argues that the statutory requirement of a margin of safety does not mandate adoption of the method suggested by St. Joe. Rather, EPA suggests, it indicates the precautionary orientation the Administrator is to bring to bear on the task of setting air quality standards. How conservative he must be in making particular judgments must, the Agency maintains, depend on such factors as the amount of uncertainty involved, the size of the population affected, and the severity of the effect. EPA argues that petitioners' claims about multiple allowances for margins of safety indicate that they have failed to recognize the difference between providing for a margin of safety and making a scientific judgment in the face of conflicting evidence.[77]

We agree with the Administrator that nothing in the statutory scheme or the legislative history requires him to adopt the margin of safety approach suggested by St. Joe.[78] Adding the margin of safety at the end of the analysis is one approach, but it is not the only possible method. Indeed, the Administrator considered this approach but decided against it because of complications raised by the multiple sources of lead exposure.[79] The choice between these possible approaches is a policy choice

---

[77] For example, EPA argues that selection of an air lead/blood lead ratio of 1:2 and assumption of a contribution to blood lead levels from non-air sources of 12 ug Pb/dl were both best estimates based on the evidence available to the Administrator, rather than attempts to provide for an additional margin of safety.

[78] Quite the contrary, the House Report on the 1977 Amendments recognized that the absence of any clear threshold below which there are no adverse health effects from exposure to a pollutant and above which there are such effects makes the margins of safety purportedly added at the end of the analysis more of an illusion than a reality. *See* H.R. Rep. No. 95-294, *supra* note 41, at 110-112.

[79] *See* 43 FED. REG. 46255, JA 2957.

of the type that Congress specifically left to the Administrator's judgment. This court must allow him the discretion to determine which approach will best fulfill the goals of the Act. As we pointed out in *Hercules Inc. v. EPA*, *supra*, 598 F.2d at 108, "Decision between the alternatives is a quintessential policy judgment within the discretion of EPA. We cannot accept [the] notion that the administrator of the agency created to protect the environment lack[s] even the *capability* to exercise the discretion with which he was entrusted by Congress." (Emphasis in original.)[80] Where, as here, the Administrator has provided an explanation of why he chose one method rather than another, and this explanation and his choice are not irrational, we must accept his decision. *See Industrial Union Dep't, AFL-CIO v. Hodgson*, *supra*, 499 F.2d at 475-476.

We also agree with the Administrator's suggestion that petitioners have ignored the distinction between scientific judgments based on the available evidence and allowances for margins of safety. In every instance in which the Administrator's judgment on a particular issue differed from petitioners' they attributed his decision to an allowance for a margin of safety. To be sure, there is no bright line that divides these two types of decisions, but they are nonetheless conceptually distinct. In any event, whatever the nature of the decision, the real test, as petitioners recognize,[81] is whether the decision is rea-

---

[80] Thus, in contrast to the approach he adopted in the lead standards rulemaking, the Administrator, in setting air quality standards for ozone, decided that adjusting the final number was a reasonable and feasible method of providing for an appropriate margin of safety. *See* 44 FED. REG. 8202, 8215-8217 (Feb. 8, 1979).

[81] Thus petitioners argue that a number of the Administrator's conclusions (the same ones they claim include allowances for margins of safety) were arbitrary and capricious, a claim that we will examine next.

sonable when examined in light of the evidence in the record. We have already found that at least one of the decisions that the petitioners attribute to an allowance for a margin of safety—the selection of the maximum safe individual blood lead level for children—satisfies this test. Accordingly, we turn to petitioners' claims that the other steps in the Administrator's analysis cannot withstand critical scrutiny.

VII. Alleged Arbitrary and Capricious Decisions

Petitioners contend that a number of the findings which constitute the very core of the Administrator's analysis violate one or more of the decisionmaking requirements of the Act. While arguing that each of these violations is sufficient ground for remand of the regulations to EPA, LIA maintains that "cumulatively they paint a picture of an agency that had prejudged the result from the very outset and was bent on adhering to its original proposal no matter what the evidence showed, the very converse of the fair and impartial rulemaking to which litigants * * * are entitled." [82]

A. *Air Lead/Blood Lead Ratio*

LIA contends that the Administrator's choice of an air lead/blood lead ratio of 1:2 as the appropriate ratio for calculating the lead standards was arbitrary and capricious. LIA's claim is largely based on its disagreement with the Administrator's interpretation of the results of three studies that have examined the relationship between air lead exposure and blood lead levels. It argues that the Administrator's analysis of these studies is inconsistent and designed solely to support his decision to arrive at an air quality standard of 1.5 ug Pb/m^3.[83] In

---

[82] Brief for petitioner LIA at 33.

[83] The results of these studies appear in a table in the Criteria Document which sets out the ratios found by several studies at various levels of air lead exposure. CD 12-25 (Table

addition, LIA contends that the Administrator erred by calculating the air lead/blood lead ratio on the basis of studies involving both adults and children, when the standards are designed to protect children. LIA maintains that the Administrator would have arrived at a ratio of 1:1.3, had he focused solely on the studies involving children.

We do not agree that the Administrator's selection of an air lead/blood lead ratio of 1:2 was arbitrary or capricious. The Criteria Document reported that air lead/blood lead ratios for the whole population, adults as well as children, range between 1:1 and 1:2, with children at the upper end of the range or even slightly above it. CD 12-38, JA 1325. And the range of ratios for children reported by the studies that were reviewed in the Criteria Document was 1:1.2 to 1:2.3. CD 12-25 (Table 12-28), JA 1312 (Table 12-28),[84] The Administrator's choice of a ratio of 1:2 for purposes of calculating the lead standards is consistent with each of these findings. Moreover, the Administrator calculated that

---

12-28), JA 1312 (Table 12-28). LIA points out that the three studies discussed by the Administrator do not show any ratios for the 1.5 ug Pb/m^3 level at which the lead standard was set. As such the Administrator estimated a ratio for each of the studies, and in doing so he used a different method for calculating the ratio for each study. LIA contends that the only consistency in his approach was that in each instance he adopted the method that would produce a ratio supporting the 1.5 ug Pb/m^3 standard.

[84] Thus there is little merit to LIA's complaint about the fact that the Administrator's calculations were based on studies which included ratios for adults as well as children. If anything, including the ratios for adults probably resulted in lower numbers since, according to both the Criteria Document and expert witnesses, children have higher air lead/blood lead ratios than do adults. *See* CD 12-38, 12-25 (Table 12-28), 12-29, JA 1325, 1312 (Table 12-28), 1316; JA 2499-2508 (Piomelli); JA 853-855 (Landrigan).

each of three particularly relevant and well-documented studies that were reviewed by the Criteria Document suggested an air lead/blood lead ratio close to 1:2. 43 FED. REG. 46250, 46254, JA 2954, 2956.[85] Finally, the Administrator's choice of a ratio of 1:2 was endorsed by several experts who participated in the rulemaking proceedings.[86] Indeed, the issue of the proper relationship between air lead exposure and blood lead levels was extensively discussed in the comments on the initial drafts of the Criteria Document, with several experts severely criticizing the suggestions in early drafts that the ap-

---

[85] The three studies selected were studies by Azar *et al.*, Griffen *et al.*, and Yankel *et al.* The Azar study was chosen because its use of personal dosimeters on the subjects' bodies to measure air lead exposure made it one of the strongest adult epidemiological studies. 43 FED. REG. 46250, JA 2952. The study by Griffin was selected because it was a well controlled clinical study of adults exposed to lead aerosol in a sealed chamber. *Id.* The Yankel study was examined because it was a well controlled study of children alone. *Id. See* CD 12-21-12-29, JA 1308-1316. The Administrator's calculations yielded ratios of 1:1.8 for the Azar study, 1:1.7 for the Griffen study, and 1:1.95 for the Yankel study. 43 FED. REG. 46250, 46254, JA 2952, 2956. We reject LIA's attempt to impute improper motives to the Administrator's use of different methods to calculate the ratio indicated by each study. The Administrator explained that the differences in approach were designed to correct for apparent errors in the studies, *see* 43 FED. REG. 46254, JA 2956, an explanation that does not strike us as irrational. Moreover, even if we were to disregard these calculations, we would still conclude that the Criteria Document and the expert testimony in the record provide adequate support for the Administrator's choice of an air lead/blood lead ratio of 1:2.

[86] *See, e.g.*, JA 2499-2508 (Piomelli); JA 427-430 (Bridbord); JA 853-855 (Landrigan); JA 125-127 (Needleman and Maher); JA 73 (National Institute for Occupational Safety and Health (NIOSH)).

propriate ratio is 1:1.[87] Given all the evidence in the record which supports the Administrator's choice of a ratio of 1:2, we would be exceeding the scope of our reviewing function if we were to agree with LIA's suggestion that the Administrator's decision was either arbitrary or capricious.[88]

B. *Changes in Method*

LIA next argues that the Administrator contravened the decisionmaking requirements of Section 307(d), 42 U.S.C. § 7607(d), by failing to explain the reasons for a change in the method he used in calculating the lead standards between the proposed and the final standards.[89] LIA correctly points out that the final standard was based on an adverse health effects threshold of 30 ug Pb/dl, whereas the proposed standards had been based on a threshold of 15 ug Pb/dl. It notes that one reason why both the proposed and the final standards nevertheless ar-

---

[87] *See, e.g.*, JA 73 (Finklea, NIOSH); JA 75 (Baker, CDC); JA 104 (Piomelli); JA 121-122 (Wallis, Texas Air Control Board); JA 127-128, 415-419 (Needleman and Maher); JA 424 (Piomelli).

[88] The source of LIA's calculation that the Administrator would have arrived at a ratio of 1:1.3 had he focused solely on the studies involving children is apparently a study by Dr. Snee of duPont Corp., submitted during the development of the Criteria Document. JA 1842-1847. This study was severely criticized both by members of EPA's SAB Lead Subcommittee and by other experts who participated in the rulemaking proceedings. *See* JA 414-419 (Needleman and Maher); JA 427-430 (Bridbord, CDC); JA 547-551 (Schwartz, N.Y. City Health Dep't); JA 553-554, 569, 432-435 (Levine); JA 455-457 (Goldsmith, Cal. Dep't of Health); JA 479-480 (Corliss, United States Public Health Service).

[89] 42 U.S.C. § 7607(d)(6)(A) requires the Administrator to give "an explanation of the reasons for any major changes in the promulgated rule from the proposed rule."

rived at an air quality standard of 1.5 ug Pb/m^3 was that the Administrator employed different statistical procedures in determining the target mean population blood level for the two standards.[90] While intimating that the change in methods was not unrelated to EPA's desire to arrive at a final standard of 1.5 ug Pb/m^3, LIA contends that the Administrator did not explain the reasons for this change in method as required by the Act. LIA further argues that the Administrator failed to reconcile his adoption of the statistical procedure used in calculating the final standard with his earlier suggestion (in the proposed standards) that this method "may overestimate the degree to which the population mean should be below the threshold blood lead level." 42 FED. REG. 63079, JA 1483. LIA maintains that the Administrator should either have corrected for the use of such an overprotective procedure or explained the reasons why he chose not to do so.

We find LIA's contentions to be without substantial merit. In evaluating the significance of these claims, we cannot help noticing that in spite of the misgivings the Administrator had expressed about the lognormal statistical procedure, both LIA and its experts endorsed the use of this procedure in their comments on the proposed standards, and in fact used it to calculate the alternative

---

[90] In calculating the proposed standards the Administrator selected the lowest reported blood lead level at which EP elevation has been detected—15 ug Pb/dl—as the targest mean population blood lead level. 42 FED. REG. 63079, JA 1483. But in calculating the final standards he first determined the adverse health effects threshold—30 ug Pb/dl—and then applied lognormal statistical procedures to obtain the target mean population blood lead level which would keep 99.5% of the children between the ages of 1 and 5 years below that blood lead level—15 ug Pb/dl. 43 FED. REG. 46252-46253, JA 2954-2955. *See* text and note at note 27 *supra*.

standards that they recommended.[91] LIA's newly discovered objection to the use of this procedure thus really seems directed at the result it produced, rather than the mere fact that the Administrator used it.[92] Be that as it may, we are satisfied that the Administrator complied with the requirements of Section 307(d). At the time he issued the proposed standards the Administrator informed the public that use of lognormal statistical procedures was an alternative approach to the method he had employed in calculating the proposed standards, and he candidly explained that he had some reservations about the procedure. 42 FED. REG. 63079, JA 1483. A fair reading of the Administrator's discussion of the issue in the final regulations suggests that the comments on the proposed standards, including the comments submitted by LIA and its experts, persuaded him to reexamine his analysis, and to conclude that his earlier misgivings about the lognormal procedure were exaggerated. 43 FED. REG. 46252-46253, JA 2954-2955. And we are satisfied that it is possible to discern the reasons why the Administrator decided to adopt this procedure from his discussion. *Id.*[93] Accord-

---

[91] *See* JA 2368-2369 (LIA); JA 2137-2139 (Cole, LIA); JA 2100-2101 (Chisholm, LIA); JA 2178 (St. Joe).

[92] It is evident from the comments cited in note 91 *supra* that if the Administrator had adopted LIA's recommendation of an adverse health effects threshold of 40 ug Pb/dl and then used the lognormal statistical procedure to determine the target mean population blood lead level, LIA would have no complaints about the use of this procedure.

[93] While the Administrator did not discuss in detail his earlier misgivings about the lognormal procedure, it is reasonable to assume that these were overcome by the endorsements of this procedure by the comments on the proposed standards. In addition, we note that one factor that had ac-

ingly, we must conclude that his discussion of the alternative methods and the reasons for the change in his approach were more than adequate to comply with the requirements of Section 307(d).

Finally, we have uncovered nothing in the record that indicates that the procedure is unreliable, or that the Administrator's decision to use it was unreasonable. Moreover, so far as we can tell, at no time during the course of the rulemaking proceedings did LIA raise any objections to, or even express any reservations about, the lognormal statistical procedure, this in spite of the misgivings the Administrator expressed in the proposed standards.[94] LIA did not even mention this issue in the petition it filed with EPA for reconsideration and stay of the lead standards. In these circumstances, remanding the regulations to EPA is totally unwarranted. LIA

---

counted for the Administrator's suggestion that the procedure might be overprotective was his feeling that there was already a margin of safety built into the selection (in the proposed standards) of the lowest reported threshold for EP elevation—15 ug Pb/dl—as the target blood lead level. 42 FED. REG. 63079, JA 1483. Since the final standards were based on an adverse health effects threshold of 30 ug Pb/dl (rather than the level at which EP elevation is first detected), the built-in safety margin that made the Administrator reluctant to use the lognormal procedure in calculating the proposed standards was no longer present.

[94] The point here is not that LIA should have known that the Administrator would adopt the lognormal procedure in calculating the final standards; it obviously had no way of predicting this. Rather, the point is that, given its detailed criticisms of other aspects of the Administrator's analysis, LIA's comments would have included its objections to the method if in fact it genuinely believed the method to be overprotective or otherwise flawed. Moreover, LIA would certainly not have used a procedure that it felt was overprotective in calculating its own recommended alternative standards.

would do well to remember the Supreme Court's admonition that "administrative proceedings should not be a game or a forum to engage in unjustified obstructionism by making [no reference to an issue] and then, after failing to * * * bring the matter to the agency's attention, seeking to have that agency determination vacated on the ground that the agency failed to consider [the matter] * * *." *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.*, 435 U.S. 519, 553-554 (1978).

C. *Insoluble and Non-Respirable Particles*

Both LIA and St. Joe argue that the Administrator acted arbitrarily and capriciously by refusing to exclude lead particles that are insoluble, or non-respirable because of their size, from the ambient air quality standards, despite the fact that this issue was brought to his attention. LIA points out that the Criteria Document suggests that particle size and solubility may affect absorption of lead emissions through the lungs.[95] Petitioners conclude from this that the Administrator should have excluded insoluble and non-respirable particles from the standards, arguing that his failure to do so is particularly unfair to stationary emission sources because a significant portion of lead emissions from such sources are of this nature. St. Joe maintains that exclusion of these particles from the standards would minimize the adverse economic impact that the lead standards will have on the industry. And LIA argues that the Administrator's response to its comments on this issue ignored the question of solubility, thereby violating the requirement that he respond to significant comments and criticisms.[96]

---

[95] *See* CD 7-13, 10-1 - 10-2, JA 1183, 1212-1213.

[96] 42 U.S.C. § 7607(d)(6)(B).

The Administrator offers a number of justifications for his decision not to exclude insoluble particles from the lead standards. First, the Administrator dismisses LIA's suggestion that he was required to respond to the claim that certain lead particles are insoluble, pointing out that very little evidence was presented to support this claim and that such evidence as there was focused on high level occupational exposures and was therefore of little relevance to the task of setting air quality standards for the whole population.[97] He further notes that studies discussed in the Criteria Document indicate that non-industry-employed populations living in the vicinity of smelters show high blood lead levels and severe health impairment,[98] and he argues that these revelations refute the suggestion that a significant portion of emissions from such sources is insoluble and cannot be absorbed into the blood. Finally, EPA contends that even if the Administrator erred in not explaining why he rejected the suggestion that he exclude insoluble particles from the standard, this was at most a harmless procedural error which is not ground for remand of the lead standards.

The Administrator also offers several justifications for his decision not to exclude from the lead standards particles which are supposedly non-respirable because they are too large. He begins by noting that these larger particles—those that are over one micron in size—constitute only a very small percentage of overall airborne lead,[99] and that the data available on particle size retention in the lungs and subsequent absorption into the bloodstream

---

[97] The Administrator points out that the only evidence on this issue was a two-page discussion. *See* JA 2212-2213 (St. Joe).

[98] CD 12-14 - 12-18, JA 1301-1305.

[99] *See* CD 6-1 - 6-4, JA 1143-1146.

is very limited.[100] Next, he points out that studies discussed in the Criteria Document and other evidence in the record indicate that these larger particles are also retained in the lungs and subsequently absorbed into the blood, although to a lesser degree than are smaller particles.[101] As such, some percentage of these larger particles are in fact respirable. In addition, the Administrator notes that the Criteria Document indicates that some portion of these larger particles are cleared from the throat and lungs, swallowed, and subsequently absorbed into the blood through the intestines.[102]

These facts alone, the Administrator argues, are sufficient to sustain the decision not to distinguish between respirable and non-respirable particles. But he also points out that one other consideration played a role in the decision and provides further support for it. The Administrator explains that in areas with high concentrations of airborne lead, such as near lead smelters or major highways, much of the lead settles on the ground and may eventually become a source of human lead exposure through ingestion of lead-contaminated food or, particularly in children, placing hands and other contaminated objects in the mouth. 43 FED. REG. 46251, JA 2953. While acknowledging that some allowance was made for the contribution of non-air sources to blood lead levels in calculating the lead standards, the Administrator stresses that the 12 ug Pb/dl estimate is merely a minimum na-

---

[100] CD 10-1, JA 1212.

[101] CD 10-1 - 10-2, JA 1212-1213; JA 2595-2596 (Needleman and Piomelli).

[102] *Id.* The Administrator also suggested, although there appears to be no evidence in the record to substantiate this, that some portion of the larger particles that fall to the ground are reintroduced into the atmosphere in smaller, more easily respirable size through natural weathering and mechanical action. 43 FED. REG. 46251, JA 2953.

tional average which does not reflect the true non-air contribution to blood lead levels near major emission sources.[103] The Administrator argues that for this reason, as well as the others previously stated, the decision not to exclude non-respirable particles was based on firm evidence that these particles do in fact contribute to blood lead levels.

We find that the Administrator's decision not to exclude insoluble particles from the lead standards was neither arbitrary nor capricious. The only information in the record on the issue of insolubility that petitioners are able to point to is a two-page discussion in St. Joe's comments on the proposed standards,[104] and even this discussion does not suggest that lead emissions from smelters or other industrial sources are insoluble. The Criteria Document merely states that the exposure of lead miners may "depend to some extent on the solubility of the lead from the ores." CD 7-13, JA 1183.[105] Given the paucity of the information presented on this question, there was nothing arbitrary or capricious about the Administrator's decision to include such particles in the lead

---

[103] *See* 43 FED. REG. 46253, JA 2955.

[104] *See* JA 2212-2213 (St. Joe). The Criteria Document states that "[m]easurements are not available to confirm the chemical form of lead emissions from stationary sources," and can make no more definite a statement than that "although the compounds generally associated with stationary sources are not particularly soluble, the possibility of conversion to more soluble compounds or accumulation of the particles in the lungs of exposed populations should not be ignored." CD 6-8, JA 1150.

[105] It goes on to point out that the "lead sulfide (PbS) in galena is insoluble, and absorption through the lung may be slight. It is not really known how readily absorption takes place. In the stomach, however, some lead sulfide may be converted to slightly soluble lead chloride, which may then be absorbed in moderate amounts." CD 7-13, JA 1183.

standards. Furthermore, LIA's contention that the Administrator was required to respond to its suggestion that insoluble particles should be excluded from the standards borders on the ludicrous. Section 307(d)(6)(B) only requires the Administrator to respond to "significant comments." LIA's unsupported claim simply did not rise to the level of a comment which required a response from the Administrator.

We also conclude that the Administrator's decision not to exclude non-respirable particles from the lead standards was reasonable and supported by the record. The Criteria Document and other evidence in the record provide an adequate basis for his determination that some portion of these respirable particles are eventually absorbed into the bloodstream, and we agree with the Administrator that this fact alone is sufficient to demonstate that his decision was neither arbitrary nor capricious.[106] As we have previously said, our task is at an end once we have ascertained that the agency "has given reasoned consideration to all the material facts and is-

---

[106] That the available data was insufficient to generate conclusions about the precise percentage of these larger particles that eventually find their way into the bloodstream is, given the preventive orientation of the statutory scheme, insignificant. *Cf. Hercules Inc. v. EPA, supra* note 32, 598 F.2d at 116-117 (agency decision on complex issue is acceptable as long as it is within the "zone of reasonableness").

We also agree with the Administrator's suggestion that the higher-than-average exposure of the population living in the immediate vicinity of major emission sources to non-air sources of blood lead was an appropriate factor to consider in making the decision. Contrary to petitioners' contentions, the mere fact that the Administrator had already provided for a non-air component does not make this double counting. The Administrator was careful to point out that the non-air contribution estimate was only a minimum national average. *See* 43 FED. REG. 46253, JA 2955; *see also* 42 FED. REG. 63080-63081, JA 1484-1485.

sues," *Greater Boston Television Corp. v. FCC, supra,* 444 F.2d at 851, and that its decision is supported by the record. In this case we are satisfied that the Administrator's decision meets both tests.[107]

VIII. Procedural Objections

LIA also raises a variety of procedural objections to the lead standards rulemaking which, in its view, mandate remand of the lead standards to EPA.

---

[107] LIA presents two other objections to the Administrator's decisions. First, it contends that he failed to respond to the evidence it presented which indicated that there are no adverse health effects at blood lead levels below 40 ug Pb/dl. Because we have already upheld the Administrator's selection of an adverse effects threshold of 30 ug Pb/dl, this claim merits little additional discussion other than to point out that the preamble to the final standards did in fact specifically address the question of adverse health effects at blood lead levels below 40 ug Pb/dl. *See* 43 Fed. Reg. 46248-46249, JA 2950-2951. No additional response to petitioner's comments was required.

Second, LIA argues that the Administrator failed to consider the evidence pointing to the alleged adverse environmental impact of the lead standards. It notes that comments submitted by NL Industries, Inc. suggested that if the lead standards forced closure of secondary smelters which produce lead principally by recycling batteries, the alternative means of disposing of these batteries may increase the volume of hazardous wastes. *See* JA 2272-2274. EPA responds by pointing out that an environmental impact statement was prepared for the lead standards, and that in it the Administrator acknowledged that the lead standards may cause short-term adverse environmental effects but concluded that the long-term environmental benefits from having the standards far outweigh these possible short-term adverse effects. *See* JA 2938-2941. In light of this conclusion, we are satisfied that the lead-battery disposal issue was not of sufficient significance to merit separate discussion in the preamble to the final standards.

A. *The Needleman Study*

LIA argues that EPA erred by relying on a study submitted after the close of the public comment period without first allowing interested parties an opportunity to comment on it. The "Needleman Study" [108] examined the relationship between lead exposure measured by lead concentration in teeth and the psychological performance of young children. The study was first mentioned by Dr. Needleman when he referred briefly to a study he had conducted but had not yet published which, he said, indicated "that children who have a mean blood lead level in the past of 35 micrograms per deciliter are significantly impaired on a large number of psychological outcomes when compared to children who had a mean level in the past of 24 micrograms, a 10 microgram difference * * *." JA 1626. The study itself was not submitted to EPA until June 7, 1978, after the close of the public comment period, and it was placed in the public docket on August 17, 1978.

LIA acknowledges that the Administrator did not mention the study in the preamble to the lead standards, but it nevertheless argues that EPA clearly relied on the study in formulating the final standards. In support of this allegation LIA notes that the preamble refers to "the possibility that nervous system damage may occur in children even without overt symptoms of lead poisoning" and the "possibility that lead exposure resulting in blood lead levels previously considered safe may in fact influence the neurological development and learning abilities of the young child." 43 FED. REG. 46246, 46255, JA 2948, 2957. Both these statements, LIA claims, are paraphrases of Dr. Neddleman's findings. In addition, LIA points to a number of internal agency memoranda which purportedly show that the agency placed increasing reli-

---

[108] *See* JA 2617-2655.

ance on the supposed low level neurological effects of lead exposure to justify the standard after it received the study.[109]

EPA disclaims any reliance on the Needleman study in the formulation of the lead standards, pointing out that its conclusions about the effects of low level blood lead concentrations on the central nervous system and psychological performance were based on other evidence in the record. In addition, EPA notes that the lead standards were not in fact based on protecting children from neurological disorders at blood lead levels of 25-30 ug Pb/dl, which is what the Needleman study found, and points out that the only neurological effects that played a role in the Administrator's analysis were the central nervous system deficits which occur at blood lead levels of 50-60 ug Pb/dl. EPA also contends that none of the intra-agency discussions of the Needleman study to which LIA refers suggests that it was being relied on in the formulation of the standards.[110] Finally, EPA argues that soliciting comments on the Needleman study was unnecessary because comments on the study would not

---

[109] LIA refers to three internal agency memoranda which it obtained through a Freedom of Information Act request. These documents were lodged with the court in connection with this case. *See* note 156 *infra*.

[110] EPA points out that in the first memorandum the reference to the Needleman study is only a minor element in a paragraph discussing the health effects of lead exposure, and the memorandum notes that the Needleman study is open to methodological criticism. *See* Appendix to Lodged Documents (hereinafter ALD) 109. The second memorandum does not even refer to the study. It merely mentioned that there was "suggestive evidence that some neurological effects may be associated with blood [lead levels below 50-60 ug Pb/dl]." ALD 115. The third memorandum merely inquires about whether the Needleman study and other evidence in the record could provide a basis for a lower standard than the 1.5 ug Pb/m^3 level that was ultimately promulgated. *See* ALD 172.

have changed the standard since the standard was not based on the study.[111] We agree.

In our view, LIA has not adduced any evidence to substantiate its claim that the Administrator relied on the Needleman study in formulating the lead air quality standards. We have already found that the Administrator's conclusions about the health effects of lead exposure —including the statements in the preamble to which LIA refers—are amply supported by the evidence in the record. Accordingly, we have no reason to reject the Administrator's disclaimer of reliance on the Needleman study.

B. *Cross-Examination*

LIA's next procedural challenge stems from the denial of its request for an opportunity to cross-examine the medical and scientific witnesses who testified in support of the then-proposed standards at the public hearings on the lead standards. Acknowledging that the Act does not provide for cross-examination, LIA argues that this case presents a situation in which "constitutional constraints" or "extremely compelling circumstances," *see Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc., supra,* 435 U.S. at 543, justify imposition of additional procedures on an agency by a reviewing court. In support of this claim LIA first alleges that EPA failed to submit the scientific issues raised by the lead standards for review by the Independent Scientific Review Committee as required by statute,[112] thereby

---

[111] EPA notes that 42 U.S.C. § 7607(d)(8) states that only procedural errors that "were so serious and related to matters of such central relevance to the rule that there is a substantial likelihood that the rule would have been significantly changed if such errors had not been made" may invalidate the regulations.

[112] We will examine this claim at a later point. *See* —— F.2d at —— (pp. 83-84) *infra.*

"foreclos[ing] an independent, objective and unbiased review of the crucial medical and scientific data[.]" [113] LIA further notes that this court has intimated that in some situations "cross-examination of live witnesses on a subject of critical importance which could not be adequately ventilated under the general procedures" may be appropriate even though not required by statute. *International Harvester Corp. v. Ruckelshaus*, 478 F.2d 615, 631 (1973). Finally, LIA contends that EPA itself demonstrated that it recognized the desirability of cross-examination on these issues by allowing "intensive and at times hostile cross-examination" of experts who testified against the proposed standards.[114] LIA argues that EPA offended "fundamental notions of fairness implicit in due process," *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 56 (D.C. Cir.), *cert. denied*, 434 U.S. 828 (1977), by refusing to permit similar cross-examination of experts who testified in favor of the standards.

As LIA itself acknowledges, it faces an extremely heavy burden in its attempt to persuade this court to impose on EPA a procedure that is not required by statute. The Supreme Court's decision in the *Vermont Yankee* case makes it absolutely clear that courts must be extremely reticent about going beyond the procedures established by Congress and requiring agencies to provide additional procedures in rulemaking proceedings. Judicial restraint in this matter is all the more important where, as here, Congress considered and deliberately decided against a particular procedure. Section 307(d)(5), 42 U.S.C. § 7607(d)(5), which governs the procedure at public hearings, was added by the 1977 Amendments to the Act. The House bill did in fact require an opportunity for cross-examination during public hearings, but the Senate bill

---

[113] Brief for petitioner LIA at 48.

[114] *Id.* at 49.

did not. The Conference Committee adopted the House bill but deleted the cross-examination provision, substituting in its place a requirement that the hearing record remain open for 30 days after the close of the hearings in order to permit parties to submit rebuttal and supplemental information. *See* H.R. Rep. No. 95-564, 95th Cong., 1st Sess. 177-178 (Conference Report) (1977). We may not ignore Congress' judgment that the crucial issues in these standard-setting proceedings can be "adequately ventilated" without providing an opportunity for cross-examination.

But even assuming for purposes of argument that we could, in appropriate circumstances, require EPA to permit cross-examination on certain issues, LIA does not even come close to sustaining its burden of demonstrating that this is a proper case for imposition of this requirement. First, as we will show later, there simply is no truth to LIA's claim that there was no independent and objective review of the medical and other scientific issues raised by the task of setting air quality standards for lead.[115] Second, we fail to see what significant additional information cross-examination would have uncovered. LIA participated in every stage of the lead standards rulemaking.[116] It had ample opportunity to submit

---

[115] *See* —— F.2d at —— (pp. 83-84) *infra*. It is also worth noting that the witnesses LIA sought to cross-examine were not in fact EPA witnesses in the sense that they were asked by the Agency to testify in support of the proposed standards. Rather, they were members of other federal agencies, *e.g.*, Dr. Landrigan (CDC), or the scientific community, *e.g.*, Drs. Piomelli and Needleman.

[116] LIA and its consultants commented on the three drafts of the Criteria Document and on the proposed standards, participated in the public hearings on the standards, and even met with EPA's Administrator to present their views on June 1, 1978. JA 2716. It is doubtful that EPA has engaged in many other rulemakings that permitted as much public participation as characterized the lead standards proceedings.

testimony and other evidence from its experts supporting its views about the health effects of lead exposure, and it did. Moreover, the statutory scheme enacted by Congress provided it with an opportunity to submit rebuttal information after the hearings on the proposed standards. In these circumstances LIA was "afforded a meaningful opportunity to be heard and to controvert the evidence. Fairness demands no more." *Ethyl Corp. v. EPA*, *supra*, 541 F.2d at 54 n.124.

Indeed, the bankruptcy of LIA's claim of procedural deprivation is revealed by its attempt to mischaracterize the proceedings at the public hearings on the proposed standards by claiming that its witnesses were subjected to intensive and hostile cross-examination. The procedure for the hearings was spelled out at the beginning of the hearings by the EPA official who presided over the hearings. Each participant presented a statement, and thereafter members of the panel (which included non-EPA experts) were allowed to ask clarifying questions.[117] Moreover, the proceedings were very informal, the witnesses did not testify under oath, the formal rules of evidence did not apply, and most of the discussion between the participants was conducted on a first-name basis. A review of the transcript of the hearing shows that panel members did ask questions after the comments by experts who supported the proposed standards as well as after the statements by experts who testified against the standards.[118] It is this exchange of ideas among peers that LIA, by a strange process of metamorphosis, transforms into "intensive and at times hostile cross-examination." Having ourselves reviewed the transcript

---

[117] *See* JA 1526-1528. The chairman indicated that written questions from the floor would be accepted if time constraints permitted. *Id.*

[118] *See* JA 1525-1839.

of the public hearings we do not agree with LIA's characterization of what transpired.

Finally, LIA's attempt to cloak its cross-examination claim in constitutional garb by invoking due process is to no avail. While the Supreme Court noted in *Vermont Yankee* that "constitutional constraints" may justify imposition of additional procedures in a rulemaking when an agency is making a "quasi-judicial" determination,[119] the Court in that case rejected the suggestion that due process could require additional procedures such as an opportunity for cross-examination in a "pure" rulemaking proceeding, such as was involved in the instant case. *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc., supra,* 435 U.S. at 542 & n.16. Accordingly, we must abide by the Supreme Court's admonition that we may not "stray beyond the judicial province to explore the procedural format or to impose upon the agency [our] own notion of which procedures are 'best' or most likely to further some vague, undefined public good." *Id.* at 549.[120] EPA's hearing pro-

---

[119] It defined this type of proceeding as one in which "a very small number of persons are ' "exceptionally affected, in each case upon individual grounds," ' * * *. *United States v. Florida East Coast R. Co.*, 410 U.S., at 242, 245, quoting from *Bi-Metallic Investment Co. v. State Board of Equalization*, 239 U.S. 441, 446 (1915)." *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.*, 435 U.S. 519, 542 (1978). There can be no question but that the lead standards rulemaking was "clearly a rulemaking proceeding in its purest form[.]" *Id.* at 542 n.16.

[120] LIA's reliance on this court's suggestion in *International Harvester Corp. v. Ruckleshaus, supra* note 29, 478 F.2d at 631, is to no avail. In the first place, that case was decided before the Supreme Court's decision in *Vermont Yankee*, and the portion of the *International Harvester* opinion that deals with the cross-examination issue may not remain good law. But even assuming that *International Harvester*'s suggestion refers to the "extremely compelling circumstances" that *Ver-*

cedures complied with the Act's requirements. Nothing more was required.

C. *Independent Scientific Review Committee*

One of the changes made by the 1977 Amendments to the Clean Air Act was the establishment of an Independent Scientific Review Committee (ISRC), to be appointed by the Administrator. This Committee was to complete a review of criteria documents and air quality standards by January 1, 1980, and thereafter at five-year intervals, and recommend appropriate changes to the Administrator. Section 109 (d) (2), 42 U.S.C. § 7409 (d) (2). LIA argues that the Administrator contravened the Act by failing to submit the Lead Criteria Document and the lead standards to the ISRC for review in spite of the fact that Congress created the Committee in order to provide an oportunity for objective evaluation of the scientific issues raised by the task of setting air quality standards.

The Administrator chartered the ISRC as a subcommittee of EPA's Science Advisory Board on January 18, 1978. By then EPA had already submitted three drafts of the Lead Criteria Document for review by the Lead Subcommittee of its Science Advisory Board and the public, the Subcommittee had substantially approved the third draft, and EPA, after considering the Subcommittee's comments, had released the final Lead Criteria Document. We agree with the Administrator that in these circumstances there was little to gain from seeking further review of the Criteria Document by the newly established ISRC. The Science Advisory Board's Lead Subcommittee was entirely composed of independent non-

---

mont Yankee says may justify imposition of additional procedures, the instant case is still distinguishable since we have concluded that cross-examination was not required for adequate ventilation of the issues presented.

EPA experts, and its review of the various drafts of the Criteria Document was extremely thorough.[121] In addition, nothing in Section 109(d) required the Administrator to resubmit the Lead Criteria Document to the new committee. Accordingly, we reject LIA's claim that the Administrator violated the statute by not doing so.

D. *Participation of Assistant Administrator Hawkins*

LIA argues that the lead standards must be invalidated because of the participation of EPA Assistant Administrator David Hawkins in the rulemaking proceedings. Hawkins is head of EPA's Office of Air, Noise, and Radiation. In that capacity he supervised development of the lead (and other) air quality standards and formally recommended adoption of the 1.5 ug Pb/m^3 standard to the Administrator.[122] Before he joined EPA Hawkins was a staff attorney with the Natural Resources Defense Council, Inc. (NRDC).[123] LIA alleges that while at NRDC Hawkins "was very much involved in the lead standard issue as an attorney for NRDC," and in this capacity "represented NRDC on the lead standard issue * * * before Congress and the National Air Quality Advisory Committee * * *." [124] And it contends that because of this prior involvement Hawkins should have been disqualified from participating in the lead standards rulemaking proceedings "under the well-established rule that a government official may not participate in a matter in which he earlier participated in a representative or investigative capacity either within or without the agency." [125] Citing this court's decision in *Amos Treat*

---

[121] *See* JA 129-346, 496-817.

[122] Affidavit of David G. Hawkins 1-4, ALD 1-4.

[123] *Id.*

[124] Brief for petitioner LIA at 41, 43.

[125] *Id.* at 41.

& Co. v. SEC, 306 F.2d 260 (D.C. Cir. 1962),[126] LIA argues that Hawkins' participation in the rulemaking proceedings violated its right to due process. In addition, LIA contends that Hawkins' participation deprived the lead standards proceedings of the appearance of fairness which this court in the *Amos Treat* case described as essential to the administrative process. The only appropriate remedy, in LIA's view, is for this court to vacate and remand the lead standards to EPA for further consideration without the participation of Assistant Administrator Hawkins.

Petitioner's objection to Hawkins' participation in the lead standards rulemaking faces a threshold obstacle which LIA must surmount before we can consider the merits of its claim. Section 307(d)(7)(B) the Act, 42 U.S.C. § 7607(d)(7)(B), provides that "[o]nly an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review." Exceptions to this requirement are permitted if the objection concerns an issue that was of central relevance to the outcome of the rule, and if it was impracticable to raise the objection during the comment period or if the grounds for the objection only arose after the comment period had expired. *Id.* LIA did not raise the issue of Hawkins' disqualification until after the final regulations had been promulgated. It first brought the the matter to the Administrator's attention on December 8, 1978, two months after the final regulations were published in the *Federal Register*, when it raised the issue in its Petition for Reconsideration and Stay of the order adopting the final lead air quality standards.[127]

---

[126] LIA also cites the Sixth Circuit's decision in *American Cyanamid Co. v. FTC*, 363 F.2d 757 (6th Cir. 1966).

[127] JA 2987-2988.

LIA presents a number of arguments in support of its view that its failure to present its objections to Hawkins' participation during the public comment period as required by statute should not preclude this court from considering the merits of the claim. First, it denies it was aware of any grounds for Hawkins' disqualification until November 27, 1978, when a newspaper reported that Hawkins was recusing himself from participating in an EPA decision concerning listing of arsenic as a hazardous pollutant under Section 112 of the Act, 42 U.S.C. § 7412.[128] Noting that the general rule governing disqualification requires such claims to be raised "as soon as practicable after a party has reasonable cause to believe that grounds for disqualification exist," *Marcus v. Director, Office of Wkrs' Comp. Programs*, 548 F.2d 1044, 1051 (D.C. Cir. 1976), LIA argues that its conduct satisfied this test since its Petition for Reconsideration was filed two weeks after the newspaper report was published. In addition, it suggests that its challenge to Hawkins' participation falls within the statutory exemption for objections that arose after the public comment period. Second, LIA contends that the issues raised by Hawkins' participation in the proceedings are of sufficient importance to invoke this court's inherent jurisdiction and responsibility "to decide whether there occurred here such an inroad upon the integrity of the decisional function of the independent agency as to require the court sua sponte to set aside the whole or any part of" the regulations. *American Public Gas Ass'n v. FPC*, 567 F.2d 1016, 1070 (D.C. Cir. 1977), *cert. denied*, 435 U.S. 907 (1978). Finally, LIA suggests that the timeliness requirement of Section 307 (d) (7) (B) does not apply to its due process challenge to Hawkins' participation in the proceedings because this is

---

[128] LIA also claims that it only became aware of Hawkins' prior involvement in the lead standards issue while at NRDC as a result of the affidavit Hawkins filed with this court in connection with this proceeding.

a claim that must be reviewed pursuant to Section 307 (d) (9) (B), 42 U.S.C. § 7607(d) (9) (B), which permits reversal of EPA actions found to be "contrary to constitutional right, power, privilege, or immunity." It reads the decision in *Porter v. Califano*, 592 F.2d 770, 780 (5th Cir. 1979),[129] construing an identical provision in the Administrative Procedure Act, 5 U.S.C. § 706(2) (B) (1976), as suggesting that this court should reach the merits of its objection to Hawkins' participation.

Taking petitioner's last argument first, we find LIA simply wrong in suggesting that Section 307(d) (9) (B), in allowing the court to set aside agency actions which violate constitutional rights, somehow releases it from the obligation to present its constitutional claims to the Agency in timely fashion, as specified by the Act. By the very terms of the statute Section 307(d) (7) (B)'s timeliness requirement applies to *all* objections, not just non-constitutional challenges. Moreover, LIA's interpretation of the statute would give parties to Clean Air Act proceedings a powerful weapon for delaying and sandbagging Agency action. They could simply refrain from presenting their constitutional objections to the Agency's action until after the Agency had announced its final decision, then raise the issue before the reviewing court and obtain a reversal of the Agency's decision, and thereby compel the Agency to institute new proceedings. It is difficult to believe that a Congress that has expressed concern about the need for expeditious attainment of the goals of the Clean Air Act[130] would give parties af-

---

[129] This case was decided by a division of the Fifth Circuit, but is erroneously referred to as a decision of this court in petitioner's brief. *See* reply brief for petitioner LIA at 25.

[130] *See* S. Rep. No. 91-1196, 91st Cong., 2d Sess 1-4 (1970). This concern was reflected in the very strict deadlines that Congress laid down for accomplishing the various tasks to be performed by both EPA and the states under the statutory scheme. *See* —— F.2d at —— (pp. 6-8) *supra*.

fected by regulations issued under the Act such a potent weapon for delaying Agency action. Furthermore, LIA seriously misconstrues the decision in *Porter v. Califano*, *supra*, if it interprets it as suggesting that a litigant may present his constitutional objection to a reviewing court after failing to bring it to the Agency's attention in timely fashion. The Fifth Circuit's statement that the "intent of Congress * * * was that courts should make an independent assessment of a citizen's claim of constitutional right when reviewing agency decision-making," 592 F.2d at 780, merely acknowledges that a reviewing court owes no deference to the agency's pronouncement on a constitutional question. It in no way suggests that a litigant who neglected to present his constitutional claim to the administrative agency in timely fashion may not be precluded from raising it before the reviewing court.[131] Accordingly, LIA's objection to Assistant Administrator Hawkins' participation in the lead standards rulemaking is properly before this court only if one of petitioner's other two arguments succeeds in preserving the challenge.

In connection with LIA's claim that it first had cause to believe Hawkins should have been disqualified after the final regulations had been published, it is important to note that LIA appears to advance two theories in support of its view that Hawkins' participation in the rulemaking was improper. Both theories are founded on a

---

[131] *See American Public Gas Ass'n v. FPC*, 567 F.2d 1016, 1069-1070 (D.C. Cir. 1977), *cert. denied*, 435 U.S. 907 (1978); *Duffield v. Charleston Center, Inc.*, 503 F.2d 512, 516 (4th Cir. 1974); *Safeway Stores, Inc. v. FTC*, 366 F.2d 795, 802 (9th Cir. 1966), *cert. denied*, 386 U.S. 932 (1967); *In re United Shoe Machinery Corp.*, 276 F.2d 77, 79 (1st Cir. 1960); *North American Airlines, Inc. v. CAB*, 240 F.2d 867 (D.C. Cir. 1956), *cert. denied*, 353 U.S. 941 (1957); *Bower v. Eastern Airlines*, 214 F.2d 623 (3d Cir.), *cert. denied*, 348 U.S. 871 (1954).

suggestion that Hawkins *may* have been biased. First, LIA invokes the doctrine of conflict of interest, pointing out that NRDC was responsible for the litigation which forced the Administrator to list lead as a Section 108 pollutant, and that NRDC was a participant in the lead standards rulemaking.[132] Under this theory the mere fact of Hawkins' past position with NRDC—a participant in the proceedings—would allegedly justify the inference of bias. Second, LIA makes much of the allegation that Hawkins himself had been "very much involved" in the lead standards issue while he was employed at NRDC and had represented NRDC in the matter. While it is possible to construe this claim as further support for LIA's conflict of interest charge, it also seems to suggest that LIA believes Hawkins' prior involvement with the lead standards raises a *prejudgment question.* Bias theoretically could be demonstrated under this theory by pointing to specific *conduct* on Hawkins' part that reveals he had made up his mind about the specific factual and legal issues raised by the standard-setting exercise before the rulemaking proceedings began. Although LIA makes little attempt to distinguish these theories, we believe they deserve separate consideration, and we conclude that only on the prejudgment claim can LIA surmount the threshold procedural barrier.

Accepting LIA's claim that Hawkins played a major role in EPA's decisionmaking, and assuming for the moment that LIA's allegation of conflict of interest can be sustained, we are unable to perceive any basis for LIA's suggestion that it could not have raised this issue

---

[132] Indeed, this appears to have been the only theory LIA presented to the Administrator in its Petition for Reconsideration. *See* JA 2987-2988. This is consistent with its claim that it only became aware of Hawkins' involvement in the lead standards issue while at NRDC after he filed his affidavit with this court in connection with this litigation.

with the Administrator during the public comment period. We must presume that LIA knew that NRDC was responsible for the litigation which led to the listing of lead as a Section 108 pollutant, if only because the preamble to the proposed lead standards specifically noted this fact.[133] Nor can LIA claim ignorance about Hawkins' involvement in the lead standards rulemaking at EPA. He was a member of the EPA panel that received testimony at the public hearings on the proposed standards, and he was specifically introduced as the Assistant Administrator for Air and Waste Management.[134] Representatives of LIA, including its counsel, were present at these hearings. Finally, it is reasonable to assume that LIA or any other group that was involved in Clean Air Act dealings with EPA knew that Hawkins had been employed by NRDC before he came to EPA. Thus LIA either knew or should have known about whatever possible conflict of interest problem may have been posed by Hawkins' participation in these proceedings before the comment period expired. Yet at no time during the two years that this rulemaking took place did LIA object to, or even ask any questions about, Hawkins' participation. If LIA really believed that Hawkins' participation raised a conflict of interest question, it would have raised the issue at the time.[135] Of course, it may

---

[133] *See* 42 FED. REG. 63076, JA 1480.

[134] *See* JA 1547-1548.

[135] The record reveals that the issue was raised at a meeting held on July 27, 1978 between EPA officials, including Assistant Administrator Hawkins, and five senators from lead-producing states to discuss the proposed standards. Senator McClure brought up the question of possible bias by Agency officials involved in the standard-setting exercise, explaining that he was mentioning the issue because he wanted EPA to know that such charges had been made. *See* JA 2728. It is fairly safe to speculate that lead industry representatives were among those who had levied these charges. This meeting

be that LIA made a conscious tactical decision not to raise this question until after the rulemaking was completed, hoping to persuade the reviewing court to remand the standards to EPA and thereby delay the rulemaking. In any event, since LIA failed to present its conflict of interest claim to EPA in timely fashion, the statute precludes it from raising this issue before this court, and so we need not address the merits of LIA's conflict of interest theory.[136]

---

was held three months before the final standards were promulgated, and long before the newspaper report about Hawkins' recusal in the arsenic proceeding appeared.

[136] We note in passing that we have some doubts about the validity of LIA's conflict of interest objection. This case does not involve a situation in which the decisionmaker or a party to which he was connected has a financial interest in the outcome of the controversy. Moreover, Hawkins resigned from NRDC before he assumed the position with EPA. The only colorable basis for a conflict of interest charge is Hawkins' immediate past association with NRDC. Ordinarily, decisionmakers are required to disqualify themselves from cases in which they have signed or actively participated in preparing a pleading or a brief, or if they were otherwise actively involved in the prior stages of the case. *Laird v. Tatum,* 409 U.S. 824, 828 (1972) (memorandum of Rehnquist, J.); *Trans World Airlines, Inc. v. CAB,* 254 F.2d 90, 91 (D.C. Cir. 1958). Hawkins' connection with the lead listing controversy involved none of these activities. Moreover, LIA's attempt to bolster its conflict of interest charge by claiming that Hawkins "represented NRDC on the lead standards issue * * * before Congress and the National Air Quality Advisory Committee * * *," brief for petitioner LIA at 43, glosses over the important distinction between an attorney appearing on behalf of a client in a court or an administrative proceeding and a spokesperson presenting an organization's position on a public issue in a public forum.

In *Laird v. Tatum, supra,* Justice Rehnquist rejected a suggestion that he should have recused himself from the case because before he became an Associate Justice of the Supreme Court he had appeared before a Senate Subcommittee "as an

To the extent that LIA's objection to Hawkins' participation in the lead standards rulemaking rests on a prejudgment theory, LIA's claim that it only became aware of the grounds for his disqualification after the final regulations were adopted is slightly more plausible. Thus, while even this claim is difficult to believe,[137] we have examined the merits of LIA's prejudgment argument. We conclude that in the circumstances presented by this case Hawkins' disqualification from the lead standards rulemaking is unwarranted.

First, nothing in the record indicates that Hawkins was involved with the particular issues raised in the lead standards rulemaking while he was at NRDC. In this connection it is important to spell out precisely what Hawkins' activities concerning lead were at NRDC. In the affidavit he filed with this court Hawkins affirms

---

expert witness for the Justice Department," 409 U.S. at 825 (which was a party in the case), and had stated the Department's position on the law relating to the subject matter of the case, and because he had made other public statements about his understanding of the law on the issues raised by the case. Noting that he had no active or formal connection with the litigation of the case while he was in the Justice Department, Justice Rehnquist concluded that his testimony on behalf of the Department was not sufficient reason for disqualifying himself from the case. The parallels between Justice Rehnquist's situation in *Tatum* and Hawkins' testimony on behalf of NRDC about the lead listing controversy undermine LIA's objection to his participation in the lead standards proceeding.

[137] For example, LIA has not explained exactly how the newspaper report about Hawkins' recusal in the arsenic proceedings alerted it to the fact that Hawkins should also have recused himself from the lead standards rulemaking, particularly since LIA claims that it only came to know of Hawkins' involvement in the lead standards issue while at NRDC after he filed an affidavit with this court in connection with this case.

that he "did not have any significant personal participation in NRDC's efforts to have EPA list lead as a Section 108 pollutant, including its judicial action against EPA, or any other NRDC activity that concerned lead." [138] Hawkins did represent NRDC at a meeting of the National Air Quality Advisory Committee held on November 14, 1974, when the NRDC lawyer responsible for the lead issue was unable to attend.[139] At this meeting he articulated NRDC's previously stated position that the Administrator was required to list lead as a Section 108 pollutant.[140] In addition, Hawkins testified on behalf of NRDC at a Senate Subcommittee hearing in 1975, and in his testimony referred to lead as an example of EPA's refusal to promulgate air quality standards for a pollutant even after the statutory criteria mandating a standard had been met.[141] This reference to the lead listing controversy was a small section of a prepared statement he read at the hearing, most of which dealt with the unrelated issue of possible amendments to the Act that would preempt state authority.[142] Hawkins re-

---

[138] Hawkins affidavit at 3, ALD 3.

[139] *Id.* at 3-4, ALD 3-4. *See* brief for *amicus curiae* Natural Resources Defense Council, Inc. at 45-46.

[140] Hawkins affidavit at 4, ALD 4.

[141] Hawkins stated:

> Changes are needed in the ambient criteria and standards sections of the Act to impel further necessary standards-setting action by EPA. * * * The agency has refused to set ambient standards for a number of pollutants, notably lead, in spite of the fact that all statutory criteria mandating a standard have been met. Litigation can force EPA to act. Indeed, we have filed a suit to compel the issuance of an ambient standard for lead. * * *

Hearings before the Subcommittee on Environmental Pollution of the Senate Committee on Public Works, 94th Cong., 1st Sess. Part 2 at 1601 (1975).

[142] *See id.* at 1600-1612.

signed from NRDC before he joined EPA, and he never appeared in or in any way participated on NRDC's behalf in the EPA proceedings to establish air quality standards for lead.

This description of Hawkins' lead-related activities while at NRDC reveals two fatal deficiencies in LIA's objection to his participation in the lead standards rulemaking. First, LIA's contention that Hawkins was "very much involved in the lead standards issue as an attorney for NRDC," [143] is a gross exaggeration. His articulation of NRDC's previously stated position on the *lead listing* controversy at two public forums hardly amounts to active involvement in this matter. Second, and more important, his testimony does not even come close to suggesting that Hawkins had prejudged the precise issues in this case because he never even adverted to them. Hawkins' statements addressed only the question whether the Act required EPA to list lead as a pollutant under Section 108, an issue that was ultimately resolved by the NRDC litigation. This question is entirely separate from the issues that were raised in the lead standards rulemaking. The former involved a narrow question of statutory interpretation—whether or not the Administrator's function to list pollutants under Section 108 is mandatory once the conditions specified by the Act are satisfied. *See Natural Resources Defense Council, Inc. v. Train, supra,* 411 F.Supp. at 867. There were no factual issues in this controversy, since EPA conceded that it had made the factual determinations required by Section 108. *Id.* The lead standards rulemaking, on the other hand, was concerned with deciding the level at which air quality standards for lead should be set. While these proceedings also raised questions of statutory construction—to be sure, of different provisions of the Act—they pri-

---

[143] Brief for petitioner LIA at 41.

marily required decisions about policy and fact, most of which involved difficult scientific and technical questions[144] As such, the issues and administrative process involved in listing lead as a Section 108 pollutant are quite separate and different from the issues and process involved in setting ambient air quality standards for lead under Section 109. And any views that Hawkins may have held or expressed concerning the lead listing controversy provide no evidence of his having prejudged, or even having any prior involvement with, the issues that confronted him in the lead standards rulemaking.[145]

LIA's inability to present any evidence to support a claim that Hawkins may have prejudged the precise factual and legal issues raised by the lead standards proceedings distinguishes this case from the "prior involvement" decisions of this and other circuits on which LIA relies. In *Amos Treat & Co. v. SEC, supra,* we ruled that it was improper for a member of the Commission to participate in an *adjudicatory proceeding* when, before he became a Commissioner, he had, as director of the Commission's Division of Corporate Finance, supervised the initiation and conduct of the investigation which resulted in the proceeding.[146] The court held that it was a

---

[144] The difference in the issues raised by the two proceedings is made clear by even a cursory comparison of the District Court opinion in the lead listing case, *Natural Resources Defense Council, Inc. v. Train,* 411 F.Supp. 864 (S.D. N.Y. 1976), with our opinion in the instant case.

[145] It is entirely conceivable that an individual who believed that the Act required the Administrator to list lead as a Section 108 pollutant might nevertheless have no views concerning the question of what level the air quality standards for lead should be.

[146] As head of the Division of Corporate Finance, he had reviewed and discussed memoranda prepared by his staff detailing the facts uncovered by their investigations and their

violation of the notion of "fair play" inherent in due process for "a member of an investigative or prosecuting staff [to] initiate an investigation, weigh its results, perhaps then recommend the filing of charges, and thereafter * * * participate in adjudicatory proceedings * * *." 306 F.2d at 266. And in *American Cyanamid Co. v. FTC*, 363 F.2d 757 (6th Cir. 1966), the Sixth Circuit disqualified Chairman Dixon of the FTC from an *adjudicatory* proceeding because he had previously served as Chief Counsel and Staff Director of a Senate Subcommittee which had conducted an investigation into many of the same legal and factual issues that were before the Commission. Significantly, the court's decision in that case was based on the depth of the Subcommittee's investigation of the precise factual issues which were presented in the proceedings before the Commission, the very active role Mr. Dixon had played in the conduct of the investigation, and the uncontroverted evidence in the record which indicated that he had formed conclusions about the particular factual issues that were before the Commission.[147]

In both these cases the intimate involvement of the decisionmakers in the investigation of the same factual

---

legal theories, and he had represented the Division before the Commission in connection with the proceeding. *See Amos Treat & Co. v. SEC*, 306 F.2d 260, 265-266 (D.C. Cir. 1962).

[147] The court pointed out that the Subcommittee had investigated the same issues that were decided by the Commission, that Mr. Dixon had personally supervised all the investigatory activities of the Subcommittee's staff, including participating in selection of witnesses, and that he had extensively cross-examined witnesses about the same factual issues that later arose in the proceedings before the Commission. Moreover, Dixon's comments and questions at the hearings, as well as a report he had a substantial role in preparing, all indicated, in the court's view, that he formed conclusions about facts that were before the Commission. *See American Cyanamid Co. v. FTC*, 363 F.2d 757, 765-766 (6th Cir. 1966).

and legal issues they were then called upon to adjudicate made it inevitable for "a disinterested observer" to conclude that they had "in some measure *adjudged the facts as well as the law* * * * in advance of hearing [the cases]." *Cinderella Career & Finishing Schools, Inc. v. FTC*, 425 F.2d 583, 591 (D.C. Cir. 1970) (emphasis added), *quoting Gilligan, Will & Co. v. SEC*, 267 F.2d 461, 469 (2d Cir.), *cert. denied*, 361 U.S. 896 (1959).[148] In contrast, Hawkins' only involvement with the *lead listing* controversy was his appearance as a spokesperson on a public issue at a public forum, and even this involvement appears to have been partly fortuitous. Nothing in his statements suggests that he had prejudged any of the *legal questions* that were presented by the lead standards rulemaking. More important, insofar as both *Amos Treat* and *American Cyanamid* require a showing that the decisionmaker had formed conclusions about *the particular facts* of the case, nothing in the record indicates that Hawkins had taken a position apparently inconsistent with an ability to judge the *factual* issues that had to be resolved in setting air quality standards for lead fairly. And there is most certainly nothing in the record which suggests that Hawkins had prejudged the issue of the level at which the air quality standards for lead should be set. Accordingly, we find no basis for re-

---

[148] Thus, in contrast, in *Safeway Stores, Inc. v. FTC*, *supra* note 131, the court refused to disqualify Chairman Dixon from another FTC adjudication even though the Senate Subcommittee of which he had been Chief Counsel had also investigated some of the issues that were before the Commission, and Mr. Dixon had questioned witnesses at a Subcommittee hearing. The court concluded that nothing in Mr. Dixon's statements indicated that he prejudged any "ultimate controverted issue," and it distinguished *American Cyanamid* on the ground of Mr. Dixon's more active role in the Subcommittee investigation of the issues in that case. *See* 366 F.2d at 801-802.

quiring Hawkins' disqualification from the lead standards proceedings on prejudgment grounds.[149]

To be sure, by publicly articulating NRDC's position that the Administrator was required to list lead as a Section 108 pollutant Hawkins may have advocated promulgation of air quality standards for lead, and such advocacy might appear to make his participation in the subsequent EPA proceeding to set the standards improper. The short answer to this view is that, according to the cases, a decisionmaker "is [not] disqualified simply because he has taken a position, even in public, on a policy issue related to a dispute, in the absence of a showing that he is not 'capable of judging a particular controversy fairly on the basis of its own circumstances.'" *Hortonville Joint School Dist. No. 1 v. Hortonville Education Ass'n*, 426 U.S. 482, 493 (1976), *quoting United States v. Morgan*, 313 U.S. 409, 421 (1941). This test has been applied in deciding disqualification questions involving judges as well as administrative agency decisionmakers participating in *adjudicatory* proceedings. *See, e.g. Laird v. Tatum*, 409 U.S. 824, 831-836 (memorandum of

---

[149] The other prejudgment cases on which LIA relies are also easily distinguished from the instant case. In *Cinderella Career & Finishing Schools, Inc. v. FTC*, 425 F.2d 583 (D.C. Cir. 1970), the court concluded that public statements by the Chairman of the FTC which appeared to refer to an adjudication then pending before the Commission indicated that he had prejudged the case. Similarly, in *Texaco, Inc. v. FTC*, 336 F.2d 754 (D.C. Cir. 1964), *vacated and remanded on other grounds*, 381 U.S. 739 (1965), Chairman Dixon gave a speech in which he referred to cases which were before the Commission. The Court ruled that "a disinterested reader of Chairman Dixon's speech could hardly fail to conclude that he had in some measure decided in advance that Texaco had violated the Act." 336 F.2d at 760. Nothing about Hawkins' statements concerning the lead listing controversy permits us to conclude that he had prejudged the issues involved in the lead standards proceedings.

Rehnquist, J.); *Antonello v. Wunsch*, 500 F.2d 1260, 1262 (10th Cir. 1974); *Goodpasture v. TVA*, 434 F.2d 760, 765 (6th Cir. 1970); *Knoll v. Socony Mobil Oil Co.*, 369 F.2d 425, 430 (10th Cir. 1966) (judges); *FTC v. Cement Institute*, 333 U.S. 683, 702-703 (1948); *Carolina Environmental Study Group v. United States*, 510 F.2d 796, 801 (D.C. Cir. 1975); *Corning Glass Works v. FTC*, 509 F.2d 293, 303-304 (7th Cir. 1975); *American Cyanamid Co. v. FTC, supra*, 363 F.2d at 765-767 (agency decisionmakers).

The rule could hardly be otherwise, particularly with respect to administrative agencies which are created for the specific purpose of accomplishing certain tasks. Agency decisionmakers are appointed precisely to implement statutory programs, and so inevitably have some policy preconceptions. *See Carolina Environmental Study Group v. United States, supra*, 510 F.2d at 801. As Professor Davis has pointed out:

> * * * A Trade Commissioner should not be neutral on anti-monopoly policies, and a Securities and Exchange Commissioner should not be apathetic about the need for governmental restrictions. * * *
>
> * * * The theoretically ideal administrator is one whose broad point of view is in general agreement with the policies he administers * * *.[150]

To be sure, a different question may be presented if it can be shown that an agency decisionmaker has exhibited the type of single-minded commitment to a particular position that makes him or her totally incapable of giving fair consideration to the issues that are presented for decision. This is not, however, such a case. Nothing in

---

[150] K. DAVIS, ADMINISTRATIVE LAW TEXT § 12.01 at 247 (3d ed. 1972). *See Ass'n of Nat'l Advertisers, Inc. v. FTC*, —— F.2d ——, —— (D.C. Cir. No. 79-1117, decided Dec. 27, 1979) (slip op. at 2) (Leventhal, J., concurring).

the record suggests that Assistant Administrator Hawkins was incapable of considering the issues raised by the lead standards proceedings fairly.

Thus far we have examined Hawkins' participation in the lead standards proceedings under the prejudgment test that has been applied in *adjudicatory* proceedings. It is, however, beyond dispute that due process may impose different procedural requirements in an adjudication than are imposed in a rulemaking. *United States v. Florida East Coast R. Co.*, 410 U.S. 224, 244-245 (1973); *United States v. Allegheny-Ludlum Steel Corp.*, 406 U.S. 742 (1976). Our opinion in *Amos Treat* explained that "[j]ust exactly how the concept of 'due process' is to be applied will vary with the type of proceeding involved * * *," *Amos Treat & Co. v. SEC, supra*, 306 F.2d at 263, and it discussed at length the reasons why the result in that case was mandated by the adjudicatory nature of the SEC proceedings. *Id.* at 263-264. *See also American Cyanamid Co. v. FTC, supra*, 363 F.2d at 766-767. LIA is unable to point to any cases involving *rulemaking proceedings* in which a court has held that a decisionmaker's prior involvement with the issues presented in the proceedings, whether within or without the agency, is sufficient ground for requiring his or her disqualification.[151] To the contrary, a division of this court recently

---

[151] *Ass'n of Nat'l Advertisers, Inc. v. FTC*, 460 F.Supp. 996 (D. D.C. 1978), *rev'd, Ass'n of Nat'l Advertisers, Inc. v. FTC, supra* note 150, is the only case we know of in which an agency decisionmaker has been disqualified from participating in a rulemaking proceeding on prejudgment grounds.

Of course, there is no *statutory* ground for such disqualification. The Administrative Procedure Act's requirement of a separation between the investigative or prosecutive functions of an agency and its decisionmaking functions, 5 U.S.C. § 554(d)(2) (1976), does not apply to informal rulemaking proceedings. *See Marketing Assistance Program, Inc. v. Bergland*, 562 F.2d 1305, 1308 (D.C. Cir. 1977); *Hoffman-*

held that *Cinderella*'s prejudgment test does not apply to rulemaking proceedings.[152] *Ass'n of Nat'l Advertisers, Inc. v. FTC*, —— F.2d —— (D.C. Cir. No. 79-1117, decided December 27, 1979). Judge Tamm's opinion for the court contains an illuminating discussion of important distinctions between rulemaking and adjudication, and the consequences of these differences for standards of disqualification, which we will not repeat here. *See id.*, —— F.2d at ——-——, ——-——, slip opinion at 16-21, 33-39. *See also id.*, —— F.2d at ——-——, slip opinion at 1-6 (Leventhal, J., concurring). And under the prejudgment test for rulemaking announced in that case—a clear and convincing showing of an unalterably closed mind on a matter critical to disposition of the proceeding—there can be no question but that Hawkins' disqualification from the lead standards rulemaking is unwarranted.[153]

IX. The Secondary Air Quality Standard

The final challenge to the Administrator's actions that we must consider is LIA's objection to his decision to promulgate a national secondary ambient air quality standard for lead of 1.5 ug Pb/m^3, the same level as the

---

LaRoche, Inc. v. Kleindienst, 478 F.2d 1, 13 (3d Cir. 1973); *Willapoint Oysters, Inc. v. Ewing*, 174 F.2d 676, 693-694 (9th Cir.), *cert. denied*, 338 U.S. 860 (1949).

[152] The test announced in *Cinderella* was "whether a disinterested observer may conclude that [the agency] has in some measure adjudged the facts as well as the law of a particular case in advance of hearing it." *Cinderella Career & Finishing Schools, Inc. v. FTC*, *supra* note 149, 425 F.2d at 591.

[153] The same result is reached under the test proposed by Judge MacKinnon's dissenting opinion—a showing by a preponderance of the evidence of substantial bias or prejudgment on any critical fact that must be resolved in formulation of a rule. *Ass'n of Nat'l Advertisers, Inc. v. FTC*, *supra* note 150, —— F.2d at ——, slip op. at 37 (MacKinnon, J., dissenting in part and concurring in part).

primary standard. The Administrator explained that this decision was based on his conclusion that the evidence on the "welfare effects" of lead exposure did not justify promulgation of a secondary standard more stringent than the primary standard. LIA argues that the Administrator had no authority to adopt the secondary standard without making supporting findings showing that the standard is necessary to protect the public welfare. It contends that this court's decision in *Kennecott Copper Corp. v. EPA*, 462 F.2d 846 (D.C. Cir. 1972), mandates remand of the secondary standard. In that case we remanded the national secondary air quality standard for sulphur dioxide because the Administrator had failed to "enlighten the court as to the basis on which he reached the * * * standard from the material in the Criteria [Document]." *Id.* at 850. LIA argues that the Administrator should have considered whether the welfare effects of lead exposure would permit him to set a secondary air quality standard higher than the primary standard. Pointing out that the primary standards are supposed to protect public health and that they are based on a 90-day averaging period, LIA argues that it follows that primary standard need be met only in inhabited areas, whereas the secondary standards must also be met in uninhabited areas. Consequently, LIA contends, the Administrator's failure to consider the possibility of setting a higher secondary standard will impose an additional burden on industrial sources located in uninhabited areas which may not be justified by the requirements of protecting the public welfare.

LIA's complaint is based on a misconception about the reach of the primary standard. As EPA notes, the primary standard must be met in all parts of the country, whether inhabited or uninhabited.[154] Thus by setting the

---

[154] LIA is unable to point to anything in either the language of the Act or its legislative history which supports its claim that primary standards only apply to inhabited areas of the country.

secondary standard at the same level as the primary standard, the Administrator imposed no additional burdens on the industry, and he properly concentrated his attention on whether the welfare effects of lead exposure justified promulgation of a more stringent secondary standard. Our decision in *Kennecott Copper*, on which LIA relies, involved an attempt by the Administrator to set a secondary standard which was *more stringent* than the primary standard without explaining the basis for this decision, *see* 36 FED. REG. 8187, and it is therefore inapposite to the instant case. Furthermore, LIA did not object to the Administrator's proposal to set the secondary standard at the same level as the primary standard either in the comments that it filed on the proposed standards or at any other time during the public comment period. Indeed, so far as we have been able to determine, none of the participants in the rulemaking proceedings commented on the proposal. Accordingly, LIA is precluded from raising this objection by the timeliness requirement of the Act.[155]

X. LIA'S MOTION TO SUPPLEMENT THE ADMINISTRATIVE RECORD

In addition to reviewing petitioners' substantive and procedural challenges to the air quality standards for lead promulgated by EPA, we are also asked to rule on a motion filed by petitioner LIA for leave to supplement the index to the administrative record compiled by the Agency. LIA seeks to include in the record 38 documents —37 of them internal EPA memoranda and the other a letter from a third party—which it claims bear directly on the questions of the fairness and rationality of the Agency's decisionmaking process and procedures.[156] The

---

[155] *See* 42 U.S.C. § 7607(d)(7)(B).

[156] This motion was originally before a motions panel of this court which deferred ruling on the motion pending selec-

motion raises an issue of first impression concerning the proper scope of an administrative record assembled under Section 307(d) of the Act.

For many years courts reviewing agency decisions have struggled with the problem of large and unwieldly administrative records, particularly in reviewing informal rulemaking. More often than not the agencies did not begin to assemble the administrative record until after the regulations were challenged, with the result that courts were forced to review "historical" records—consisting of after-the-fact attempts to reconstruct the agency's decisionmaking process. A major defect of this approach was that the court was often unable to determine which of the large number of documents that were dumped into the record played a significant role in the agency's decision. Moreover, the agency could attempt to shore up inadequately justified positions by adding *post hoc* rationalizations to the record. Finally, participants in the rulemaking were not afforded an opportunity to comment on the materials that the agency considered relevant to the decision. In 1975 an EPA attorney published an article detailing these and other shortcomings of the "historical" approach to compiling the record. Pedersen, *Formal Records and Informal Rulemaking*, 85 YALE L. J. 38 (1975). He recommended that this approach be replaced by a "procedural" approach to recordmaking, whereby the agency would compile the record as the rulemaking progressed and the record would be closed

---

tion of the panel to consider the merits of petitioners' objections to the lead standards. We subsequently ruled that the documents should be lodged with the court in a separate appendix (the Appendix to Lodged Documents) pending a determination on whether they should be included in the administrative record, and we asked the parties to address in their briefs the question of the relevance of these documents and the issues they raise. *Lead Industries Ass'n v. EPA*, D.C. Cir. No. 78-2201 (Order of May 8, 1979).

when the final rule was promulgated. This record would then be the exclusive record for the agency's decision and judicial review. *Id.* at 78-82. Congress, in enacting Section 307(d), adopted these recommendations,[157] and required EPA to include in the record "all data, information, and documents" on which the rule relies.[158] In this

---

[157] The House Report explains that "[b]y and large, [section 307(d)] represents a legislative adoption of the suggestions for a rulemaking record set forth in a law review article dealing with EPA (Pederson, 'Formal Records and Informal Rulemaking,' 85 *Yale L. J.* 38 (1975).)" H.R. Rep. No. 95-294, *supra* note 41, at 319.

[158] 42 U.S.C. § 7607(d)(3)(C). The recordmaking provisions of § 307(d) state:

> (2) Not later than the date of proposal of any action to which this subsection applies, the Administrator shall establish a rulemaking docket for such action (hereinafter in this subsection referred to as a "rule"). Whenever a rule applies only within a particular State, a second (identical) docket shall be simultaneously established in the appropriate regional office of the Environmental Protection Agency.
>
> (3) In the case of any rule to which this subsection applies, notice of proposed rulemaking shall be published in the Federal Register, as provided under section 553(b) of Title 5, shall be accompanied by a statement of its basis and purpose and shall specify the period available for public comment (hereinafter referred to as the "comment period"). The notice of proposed rulemaking shall also state the docket number, the location or locations of the docket, and the times it will be open to public inspection. The statement of basis and purpose shall include a summary of—
>
> (A) the factual data on which the proposed rule is based;
>
> (B) the methodology used in obtaining the data and in analyzing the data; and

[continued]

case EPA compiled a record in the manner required by the statute, and certified the index to the record.

(C) the major legal interpretations and policy considerations underlying the proposed rule.

The statement shall also set forth or summarize and provide a reference to any pertinent findings, recommendations, and comments by the Scientific Review Committee established under section 7409(d) of this title and the National Academy of Sciences, and, if the proposal differs in any important respect from any of these recommendations, an explanation of the reasons for such differences. All data, information, and documents referred to in this paragraph on which the proposed rule relies shall be included in the docket on the date of publication of the proposed rule.

(4)(A) The rulemaking docket required under paragraph (2) shall be open for inspection by the public at reasonable times specified in the notice of proposed rulemaking. Any person may copy documents contained in the docket. The Administrator shall provide copying facilities which may be used at the expense of the person seeking copies, but the Administrator may waive or reduce such expenses in such instances as the public interest requires. Any person may request copies by mail if the person pays the expenses, including personnel costs to do the copying.

(B)(i) Promptly upon receipt by the agency, all written comments and documentary information on the proposed rule received from any person for inclusion in the docket during the comment period shall be placed in the docket. The transcript of public hearings, if any, on the proposed rule shall also be included in the docket promptly upon receipt from the person who transcribed such hearings. All documents which become available after the proposed rule has been published and which the Administrator determines are of central relevance to the rulemaking shall be placed in the docket as soon as possible after their availability.

(ii) The drafts of proposed rules submitted by the Administrator to the Office of Management and Budget

After the final standards were promulgated LIA filed a request under the Freedom of Information Act (FOIA),

---

for any interagency review process prior to proposal of any such rule, all documents accompanying such drafts, and all written comments thereon by other agencies and all written responses to such written comments by the Administrator shall be placed in the docket no later than the date of proposal of the rule. The drafts of the final rule submitted for such review process prior to promulgation and all such written comments thereon, all documents accompanying such drafts, and written responses thereto shall be placed in the docket no later than the date of promulgation.

(5) In promulgating a rule to which this subsection applies (i) the Administrator shall allow any person to submit written comments, data, or documentary information; (ii) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions; (iii) a transcript shall be kept of any oral presentation; and (iv) the Administrator shall keep the record of such proceeding open for thirty days after completion of the proceeding to provide an opportunity for submission of rebuttal and supplementary information.

(6) (A) The promulgated rule shall be accompanied by (i) a statement of basis and purpose like that referred to in paragraph (3) with respect to a proposed rule and (ii) an explanation of the reasons for any major changes in the promulgated rule from the proposed rule.

(B) The promulgated rule shall also be accompanied by a response to each of the significant comments, criticisms, and new data submitted in written or oral presentations during the comment period.

(C) The promulgated rule may not be based (in part or whole) on any information or data which has not been placed in the docket as of the date of such promulgation.

(7) (A) The record for judicial review shall consist exclusively of the material referred to in paragraph (3), clause (i) of paragraph (4) (B), and subparagraphs (A) and (B) of paragraph (6).

5 U.S.C. § 552 (1976), for all documents in EPA's possession relating to the lead standards. After reviewing the documents it received, LIA concluded that it wished to include 38 documents in the administrative record, and it filed a request with EPA to this end. EPA denied the request, and thereafter LIA filed the instant motion. The documents involved can be divided into three groups. The first group, Nos. 6, 9, 12, 15, 21-26, 33-38 (the Hawkins documents) are all supposed to show the role played by EPA Assistant Administrator Hawkins in the lead standards rulemaking. LIA argues that they are relevant to its claim that Hawkins should have been disqualified from participating in the rulemaking. The second set of documents, Nos. 8, 16-20, 30-33 (the economic evaluation documents), discuss the economic effects of the proposed standards. LIA contends that these documents show that EPA examined the economic impact of the lead standards, and it maintains that they should be included in the record because they are relevant to its arguments concerning the economic effects of the standards on the lead industry. The third set of documents, Nos. 1-5, 7, 10, 11, 13, 14, 27-29 (the staff opinions) are intra-agency memoranda [159] which LIA claims bear directly on the questions of the fairness and rationality of the Agency's decisionmaking process.

LIA rightly points out that the legislative history of Section 307(d) cautions the Agency against attempting to create a one-sided record by excluding from it material unfavorable to the Agency's position. H.R. Rep. No. 95-294, *supra*, at 319-320. And it notes, again correctly, that the legislative history acknowledges that parties have used the FOIA as an informal discovery device in rule-

---

[159] All but one of these documents are internal EPA memoranda, notes, and briefing papers. Document No. 27 is a letter from the Texas Air Control Board to Senators Tower and Bentsen.

making proceedings. *Id.* at 320. LIA then argues that its attempt to supplement the record with documents uncovered through a FOIA request is precisely what Congress intended should happen.

LIA's reasoning is correct, so far as it goes, but it does not go far enough. Its FOIA request was not filed until *after* the final rule was promulgated, and by this time the record was closed. Nothing in the statute or its legislative history indicates that a party or the agency may reopen the record by placing additional materials (other than those *required* by the statute and wrongfully omitted by EPA) in the docket after promulgation of the rule. *See American Petroleum Institute v. Costle*, 609 F.2d 20, 22-23 (D.C. Cir. 1979). The passage in the legislative history of Section 307(d) on which LIA relies merely directs EPA to coordinate its procedures for dealing with FOIA requests with the recordmaking provisions of the statute. H.R. Rep. No. 95-294, *supra*, at 320. And it suggests that LIA should have filed its FOIA request during the interval between publication of the proposed and the final rules. Not having done so, it cannot now attempt to supplement the administrative record on appeal. Section 307(d)(7)(A), 42 U.S.C. § 7607(d)(7)(A).[160]

---

[160] Our disposition of this motion makes it unnecessary for us to reach the question whether EPA rightly refused to include these documents in the record because they are internal agency documents which are ordinarily not part of the administrative record. *See Nat'l Courier Ass'n v. Board of Gov. of Fed. Reserve Sys.*, 516 F.2d 1229, 1241-1243 (D.C. Cir. 1975).

We also note that a different case would have been presented if LIA had in fact complied with the statutory scheme and filed its FOIA request before the record was closed, but was unable to obtain these documents until after the final regulations were promulgated because of delays in processing its FOIA request.

The Hawkins documents may, however present a special case. Since LIA claims that it only became aware of the grounds for Hawkins' disqualification after the final regulations were promulgated, it obviously could not have filed a FOIA request for these documents before then. EPA agrees with LIA that these documents should be before the court, and it proposed a solution whereby these documents would be lodged with the court as part of a supplemental court record, separate from the administrative record. In this manner the documents would be available to the court in passing on the issue of Hawkins' disqualification, and at the same time the record-making scheme established by the Act would be preserved. LIA has no objection to this proposal. Although we see no need for creating a separate record, we agree that the Hawkins documents are properly before the court for the sole purpose of ruling on LIA's challenge to Hawkins' participation in the rulemaking proceedings.[161] Accordingly, we affirm EPA's decision to exclude all 38 documents from the administrative record and, in addition, direct that Documents 6, 9, 12, 15, 21-26, 33-38 (the Hawkins documents) be lodged with the court.[162]

---

[161] The Hawkins documents are relevant to the disagreement between EPA and LIA about the significance of the role Hawkins played in the rulemaking proceeding. Our resolution of the issue of Hawkins' disqualification made it unnecessary for us to decide which of the two parties properly characterized Hawkins' role. We simply assumed for purposes of deciding the disqualification issue that LIA was correct in claiming that Hawkins played a major role in the decisionmaking process at EPA. *See* —— F.2d at —— (p. 89) *supra*.

[162] None of the excluded documents add anything to the merits of LIA's challenges to the Administrator's decisions. Its argument about the economic effects of the lead standards presents an issue of statutory interpretation. We do not need to review the economic evaluation documents in deciding this

XI. CONCLUSION

The national ambient air quality standards for lead were the culmination of a process of rigorous scientific and public review which permitted a thorough ventilation of the complex scientific and technical issues presented by this rulemaking proceeding. Interested parties were allowed a number of opportunities to participate in exploration and resolution of the issues raised by the standard-setting exercise. EPA, and ultimately the public whose health these air quality standards protect, have benefitted from their contribution. To be sure, even the experts did not always agree about the answers to the questions that were raised. Indeed, they did not always agree on what the relevant questions were. These disagreements underscore the novelty and complexity of the issues that had to be resolved, and both the EPA and the participants in the rulemaking proceeding deserve to be commended for the diligence with which they approached the task of coming to grips with these difficult issues.

We have accorded these cases the most careful consideration, combining as we must careful scrutiny of the evidence in the record with deference to the Administrator's judgments. We conclude that in this rulemaking proceeding the Administrator complied with the substantive and procedural requirements of the Act, and that his decisions are both adequately explained and amply supported by evidence in the record. Accordingly, we reject petitioners' claims of error. The regulations under review herein are

Affirmed.

---

question. Similarly, the documents included the administrative record provide an adequate basis for our review of the Agency's decision. The staff opinions that LIA wants to include in the record do not reveal any new information, nor do they suggest that EPA acted for improper reasons.

APPENDIX B

Title 40—Protection of Environment

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

SUBCHAPTER C—AIR PROGRAMS

[FRL 937-5]

Part 50—National Primary And Secondary Ambient Air Quality Standards

National Primary And Secondary Ambient Air Quality Standards For Lead

AGENCY: Environmental Protection Agency.

ACTION: Final rulemaking.

SUMMARY: EPA is setting a national ambient air quality standard for lead at a level of 1.5 micrograms lead per cubic meter of air (μg Pb/m^3), averaged over a calendar quarter. This final rulemaking follows a 1976 court order to list lead as a criteria pollutant for the development of an ambient standard, and the Agency's issuance of a proposed standard on December 14, 1977. In response to comments received on the proposed standard, EPA has changed the averaging period for the standard from a calendar month to a calendar quarter, and has clarified the health basis used in selecting the standard level.

In establishing the level of the final standard, EPA has determined that young children (age 1-5 years) should be regarded as a group within the general population that is particularly sensitive to lead exposure. The final standard for lead in air is based on preventing most children in the United States from exceeding a blood lead level of 30 micrograms lead per deciliter of blood (μg Pb/dl). Blood lead levels above 30 μg Pb/dl are associated with the impairment of heme synthesis in cells indicated by elevated erythrocyte protoporphyrin (EP), which EPA regards as adverse to the health of chronically exposed children. There are a number of other

PREVIOUS PAGE WAS BLANK

adverse health effects associated with blood lead levels above 30 μg Pb/dl, in children as well as in the general population, including the possibility that nervous system damage may occur in children even without overt symptoms of lead poisoning.

DATES: Effective: October 5, 1978. After promulgation, States will have nine months (until July 5, 1979), to prepare and submit to EPA plans for attainment of the standard by no later than October of 1982. EPA's final regulations for the development of State implementation plans appear elsewhere in this FEDERAL REGISTER.

FOR FURTHER INFORMATION CONTACT: Mr. Joseph Padgett, Director, Strategies and Air Standards Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, N.C. 27711, telephone 919-541-5204.

Availability Of Related Information

A docket (No. OAQPS-77-1) containing the information used by EPA in the development of the proposed standard is available for public inspection and copying between 8 a.m. and 4:30 p.m., Monday through Friday, at EPA's Central Docket Section, Room 2903B, Waterside Mall, 401 M Street SW., Washington, D.C. 20460.

The Federal reference method for collecting and measuring lead and its compounds in the ambient air is published in appendix G to this promulgation. This FEDERAL REGISTER also contains proposed regulations under 40 CFR Parts 51 and 53 for equivalent lead air monitoring methods, final rules for the development of State implementation plans promulgated under 40 CFR Part 51, and an advance notice of proposed rulemaking under 40 CFR Part 51 for ambient monitoring in the vicinity of certain industrial plants with lead emissions. Additional information for the development of the State implementation plans is contained in the document Supplementary Guidelines for Lead Implementation Plans. The en-

vironmental and economic impacts of implementing this standard are described in an environmental impact statement and an economic impact assessment. These documents are available for public inspection and copying at the Central Docket Section (address above). Copies may be obtained upon request from Mr. Joseph Padgett at the above address.

The documents Air Quality Criteria for Lead and Control Techniques for Lead Air Emissions were issued at the time of proposal. The Control Techniques Document is available upon request from Mr. Joseph Padgett at the above address. The Air Quality Criteria Document can be obtained from: Mr. Michael Berry, Environmental Criteria and Assessment Office, MD-52, Office of Research and Development, U.S. Environmental Protection Agency, Research Triangle Park, N.C. 27711, telephone 919-541-2266.

SUPPLEMENTARY INFORMATION:

Background

Lead is emitted to the atmosphere by vehicles burning leaded fuel and by certain stationary sources. Lead enters the human body through ingestion and inhalation with consequent absorption into the bloodstream and distribution to all body tissues. Clinical, epidemiological, and toxicological studies have demonstrated that exposure to lead adversely affects human health.

EPA's initial approach to controlling lead in the air was to limit the lead emissions from automobiles, the principal source of lead air emissions. Regulations for the phasedown of lead in the total gasoline pool were promulgated in 1973, and, following litigation, modified and put into effect in 1976. The Agency has also established regulations requiring the availability of no-lead gasoline for catalyst-equipped cars. EPA also intended to control emissions from certain categories of industrial point sources under section 111 of the Clean Air Act.

In 1975, the National Resources Defense Council (NRDC) and others brought suit against EPA to list lead under section 108 of the Clean Air Act as a pollutant for which air quality criteria would be developed and a national ambient air quality standard established under section 109 of the Act. The Court ruled in favor of NRDC. (*NRDC, Inc. et al.* v. *Train,* 411 F. Supp. 864 (S.D.N.Y., 1976) aff'd 545 F.2d 320 (2d Cir. 1976). EPA listed lead on March 31, 1976, and proceeded to develop air quality criteria and the proposed standard.

On December 14, 1977, EPA proposed a standard of 1.5 μg Pb/m^3, calendar month average, proposed the Federal reference method for monitoring air lead levels, issued the documents Air Quality Criteria for Lead and Control Techniques for Lead Air Emissions and proposed regulations for State implementation plans. EPA invited public comments during the period from December 14, 1977, to March 17, 1978, on the standard, reference method, and the SIP regulations. Additional comments on these matters were provided to EPA at a public hearing held on February 15-16, 1978.

Legislative Requirements For National Ambient Air Quality Standards

Sections 108 and 109 of the Clean Air Act govern the development of national ambient air quality standards. Section 108 instructs EPA to document the scientific basis for the standard:

> Section 108(a)(2). The Administrator shall issue air quality criteria for an air pollutant within 12 months after he has included such pollutant in a list under paragraph (1). Air quality criteria for an air pollutant shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities. The criteria for an air

pollutant, to the extent practicable, shall include information on—

(A) Those variable factors (including atmospheric conditions) which of themselves or in combination with other factors may alter the effects on public health or welfare of such air pollutant;

(B) The types of air pollutants which, when present in the atmosphere, may interact with such pollutant to produce an adverse effect on public health or welfare; and

(C) Any known or anticipated adverse effects on welfare.

Section 109 addresses the actual setting of the standard:

Section 109(b)(1). National primary ambient air quality standards, prescribed under subsection (a) shall be ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health. Such primary standards may be revised in the same manner as promulgated.

(2) Any national secondary ambient air quality standard prescribed, under subsection (a) shall specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air. Such secondary standards may be revised in the same manner as promulgated.

In order to conform to the requirements of section 109, EPA has based the level of the lead air quality standard on information presented in the criteria document pertaining to the health and welfare implications of lead air pollution. This is in contrast to other sections of the Act under which EPA

considers economic costs and technical availability of air pollution control systems in determining emissions limitations. It is clear from section 109 that the Agency should not attempt to place the standard at a level estimated to be at the threshold for adverse health effects, but should set the standard at a lower level in order to provide a margin of safety. EPA believes that the extent of the margin of safety represents a judgment in which the Agency considers the severity of reported health effects, the probability that such effects may occur, and uncertainties as to the full biological significance of exposure to lead.

Comments resulting from external review of the air quality criteria and the proposed standard highlight disagreements on a number of areas critical to EPA's rationale for the standard. However, the scientific data base provided in the document Air Quality Criteria for Lead is an extensive as that for any other regulated air pollutant. Also, at every stage of development of the air quality criteria and the standard, EPA has facilitated and received broad external participation. EPA regards as inevitable the presence of scientific disagreement and uncertainty about key factors relevant to environmental standards. Provisions of the Act requiring timely promulgation of the standard, and requirements for periodic future review of air quality criteria and standards indicate congressional intent that the Agency proceed even where scientific knowledge is not complete or full scientific consensus is absent.

Summary Of General Findings From Air Quality Criteria For Lead

Following the listing of lead as a criteria pollutant, EPA developed the document, Air Quality Criteria for Lead. In the preparation of this document, EPA provided opportunities for external review and comment on three successive drafts. The document was reviewed at three meetings of the Subcommittee on Scientific Criteria for Environmental Lead of EPA's Science Advisory Board. Each of these meetings

was open to the public and a number of individuals presented both critical review and new information for EPA's consideration. The final criteria document was issued on December 14, 1977.

From the scientific information in the criteria document, EPA draws conclusions in several key areas with particular relevance for the ambient air quality standard for lead.

1. There are multiple sources of lead exposure. In addition to air lead, these sources include: Lead in paint and ink, lead in drinking water, lead in pesticides, and lead in fresh and processed food.

2. Exposure to air lead can occur directly by inhalation, or indirectly by ingestion of lead contaminated food, water, or nonfood materials including dust and soil.

3. There is significant individual variability in response to lead exposure. Even within a particular population, individual response to lead exposure may vary widely from the average response for the same group. Certain subgroups within the general population are more susceptible to the effects of lead or have greater exposure potential. Of these, young children represent a population of foremost concern.

4. Three systems within the human body appear to be most sensitive to the effects of lead—the blood-forming or hematopoietic system, the nervous system, and the renal system. In addition, lead has been shown to affect the normal functions of the reproductive, endocrine, hepatic, cardiovascular, immunologic, and gastrointestinal systems.

5. The blood lead level thresholds for various biologic effects range from the risk of permanent, severe, neurological damage or death as blood leads approach and exceed 80 to 100 μg Pb/dl in children down to the inhibition of an enzymes system as low as 10 μg Pb/dl.

6. Lead is a stable compound, ubiquitously distributed, which persists and accumulates both in the environment and in the human body. In developing the proposed standard,

EPA used these findings to arrive at a standard level of 1.5 μg Pb/m^3, calendar month average. This level was derived from the Agency's judgment that the maximum safe blood lead level (geometric mean) for a population of young children was 15 μg Pb/dl and, of this amount, 12 μg Pb/dl should be attributed to nonair sources. The difference of 3.0 μg Pb/dl was estimated to be the allowable safe contribution to mean population blood lead from lead in the air. With epidemiological data indicating a general relationship of 1:2 between air lead (μg Pb/m^3) and blood lead (μg Pb/dl), EPA determined that the level for the proposed standard should be 1.5 μg/m^3.

Summary of Anticipated Impacts

While the level of the standard is based on health considerations, EPA has conducted economic and environmental studies to assess the potential impacts of the standard selected. EPA estimates that the existing regulations for the phase-down of lead in gasoline, combined with the increasing use of no-lead gasoline for catalyst-equipped cars, will result in attainment of the standard in urban areas where automobile exhaust is the dominant source of air lead. No additional pollution controls are anticipated for these areas.

EPA's economic analysis does indicate that there may be significant problems in attainment of the standard in the vicinity of nonferrous smelters and other large industrial sources of lead emissions. This assessment is based, however, on studies using general emission factors and plant configurations, combined with dispersion modeling. In the development of State plans to implement the standard, EPA is encouraging affected industries and State agencies to gather plant-specific technical data, ambient air quality data, and assessments of alternative engineering controls. With this information, the Agency will be able to more accurately evaluate the impact of the standard and better consider approval of alternative approaches to emission control in the State plans.

Also, EPA is encouraging affected firms and State agencies to evaluate in the early design phase, strategies which take into consideration the workplace standard for airborne lead which will be promulgated by the Occupational Health and Safety Administration (OSHA). EPA believes that this appraoch will facilitate application of control technologies which meet the requirements of both agencies. In working with OSHA to estimate the combined impact of the OSHA and EPA standards in coordinating compliance strategies, and in reviewing State plans implementing the ambient standard, EPA intends to avoid an approach which would foster uncertainty in the investment decisions of affected firms.

The Agency will make every effort to insure that all opportunities to avoid plant closures are examined, while at the same time assuring protection from clear risks to the public health.

Summary of Comments Received

During the comment period from December 14, 1977, to March 17, 1978, and at the public meeting on February 15-16, 1978, EPA received 95 written and oral comments addressing the proposed standard or the requirements for State implementation plans. All comments opposing the standard as excessively stringent (25) came from representatives of affected industries, and 20 of these counter-proposed 5.0 μg Pb/m^3, calendar quarter average, as the appropriate level for the standard.

5.0 mg Pb/m^3, calendar quarter average, as the appropriate level for the standard.

Comments Received Opposing the Proposed Standard of 1.5 μg/m³ Calendar Month Average as Excessively Stringent

Company	Op-posed[1]	En-dorsed[2]
Amax Lead & Zinc, Inc.	X	X
American Mining Congress	X	X
American Petroleum Institute	X	
ASARCO	X	X
Associated Octel Co., Ltd.	X	X
Battery Council International	X	X
Bethlehem Steel Corp.	X	X
Bunker Hill Co.	X	X
C & D Batteries Division	X	X
E. I. du Pont de Nemours & Co., Inc.	X	X
ESA Laboratories, Inc.	X	X
Ethyl Corp.	X	X
General Battery Corp.	X	X
General Motors Corp.	.....	
Getty Refining & Marketing Co.	X	
HECLA Mining Co.	X	
Houston Chemical	X	X
Hunt Oil Co.	X	
Kerr-McKee Corp.	.....	
Lead Industries Association	X	X
Nalco Chemical	X	X
N L Industries, Inc.	X	X
Prestolite Battery Divison	X	X
Secondary Lead Smelters Association	X	X
Shell Oil Co.	X	
St. Joe Minerals Corp.	X	X
Texaco, Inc.	X	X
United Machinery Group	.....	
Vulcan Materials Co.	.....	

[1] 1.5 μg/m³, calendar month.

[2] 5.0 μg/m³, calendar quarter (or other averaging period).

SUMMARY: Forty-five comments received from 29 corporations or their representatives; 25 of the 29 firms opposed the proposed standard of 1.5 $\mu g/m^3$, calendar month average; 20 endorsed an alternative standard of 5.0 $\mu g/m^3$, calendar quarter average (or other averaging period).

Four comments opposed the proposed standard on the grounds that it was not sufficiently protective of health.

Comments Received Opposing Proposed Lead Air Quality Standard of 1.5 $\mu g/m^3$, Calendar Month Average, In Favor of a More Stringent Standard

Natural Resources Defense Council
Dr. Sergio Piomelli, Director, Pediatric Hematology, New York University Medical Center Public Interest Campaign
University of Connecticut School of Medicine

Comments supporting the level of the proposed standard (17) came from the medical community, Federal agencies, State and local public health agencies, and public interest groups.

Comments Received Endorsing Proposed Lead Air Quality Standard of 1.5 $\mu g/m^3$, Calendar Month Average

State And Local Agencies

California Department of Health
Massachusetts Department of Public Health
New York State Department of Environmental Conservation
New York City Department of Environmental Protection
Tennessee Department of Public Health
Wisconsin Department of Natural Resources

Federal Agencies

Center for Disease Control, Public Health Service
Department of Transportation
Food and Drug Administration
Occupational Safety and Health Administration

Public Interest Groups and the Medical Community

Committee on Environmental Hazards, American Academy of Pediatrics
D.C. Committee for Lead Elimination in the District
League of Women Voters of the United States
National Urban League
Herbert Needleman, Boston Children's Hospital Medical Center
University of North Carolina School of Public Health

In addition, EPA has received numerous comments and correspondence on the proposed standard after the official end of the comment period. Though EPA does not have a legal obligation to review these documents, it has, in the interest of fostering full public participation in the rulemaking process, reviewed these comments and correspondence as time permitted. As with all other documents considered or examined by EPA as part of its decision process, these documents have been placed in the public docket and have become part of the administrative record of this decision.

The comments received by EPA did not challenge three aspects of the proposed standard:

1. The basic structure of the rationale used by the Agency in deriving the level of the proposed standard.

2. The selection of young children in a population particularly at risk to lead exposure.

3. The attribution of 12 μg Pb/dl and of the target mean population blood lead level of 15 μg Pb/dl to normal sources of lead for the purposes of setting the air standard.

Significant comments were received, however, on the following key areas relating to the standard:

1. The elevation of erythrocyte protoporphyrin (EP) as the first adverse health effect with increasing lead exposure rather than the decline of hemoglobin levels.

2. The blood lead threshold level for elevated EP.

3. The incidence of health effects in populations residing in the vicinity of industrial sources of lead particulate emissions.

4. The relationship describing the response of lead in the blood to lead in the air.

5. The statistical form and averaging period for the standard.

6. The appropriate margin of safety.

7. The limitation of the standard to the respirable fraction of total air lead particles.

8. The economic impact of the standard.

9. The State implementation plan regulations.

10. The Federal reference method for monitoring lead air quality.

11. The administrative procedures employed by EPA in the development of the standard and the provision for public participation.

A review of the comments received and their disposition has been placed in the rulemaking docket (OAQPS-77-1) for public inspection. The following paragraphs summarize the significant comments and present the Agency's findings.

The Health Significance of Erythrocyte Protoporphyrin Elevation

Ten commenters disagreed with EPA's conclusion that the impairment of heme synthesis indicated by elevated erythrocyte protoporphyrin (EP) constituted an adverse health effect. Reasons for this disagreement included:

1. An elevated level of EP is not itself toxic to the cells in blood or other tissues.

2. EP elevation, while indicating a change in heme synthesis, does not indicate an insufficient production of heme, or hemoglobin.

3. EP elevation and the alteration of heme synthesis does not imply impairment of other mitochondrial functions.

4. EP elevation is not associated with impairment of other heme proteins, particularly cytochrome P-450.

5. Elevated EP may be caused by conditions other than exposure to lead, particularly iron deficiency.

Five commenters agreed with EPA's conclusions about the health significance of elevated EP citing the following arguments:

1. The interference of lead in a fundamental cellular metabolic function to the extent that there is accumulation of a substrate is physiological impairment, even without the presence of clinical evidence of disease.

2. It is prudent medical practice to intervene where subclinical indicators of physiological impairment are present.

3. The impairment of heme synthesis resulting from genetic or dietary factors places a child at enhanced risk to lead exposure.

4. There is evidence to suggest that impaired heme synthesis may affect the function of neural or hepatic tissue even at levels where heme production is sufficient for hematopoiesis.

Agency Response

EPA agrees with the comments received that the initial elevation of EP as a result of exposure to lead, while indicating an impairment of heme synthesis, may not be a disease state or be seen as a clinically detectable decline in performance. However, the criteria document points out (p.1-13) that this impairment does increase progressively with lead dose.

The hematological effects described above are the earliest physiological impairments encountered as a function of increasing lead exposures as indexed by blood lead elevations; as such, those effects may be considered to represent critical effects of lead exposure. Although it may be argued that certain of the initial hematological effects (such as ALAD inhibition) constitute relatively mild, nondebilitating symptoms at low blood lead levels, they nevertheless signal the onset of steadily intensifying adverse effects as blood lead elevations increase. Eventually, the hematological effects reach such magnitude that they are of clear-cut medical significance as indicators of undue lead exposure.

The fact that other conditions, such as iron deficiency may also impair heme synthesis, does not obviate concern that lead is interfering with an essential biological function. There is the possibility that a nutritional deficiency is an additional stress to the heme synthetic system which may increase the sensitivity of a child to the adverse effects of lead exposure.

EPA notes that there is general agreement that heme and heme-containing proteins play important roles in the oxygen fixation pathways in all cells. While the effects of low-level lead exposure on the heme synthetic pathway in erythroid tissue have been extensively studied in part because of the ease with which this tissue may be obtained, other cellular metabolic system utilizing heme are less well understood. EPA does not have sufficient information to conclude that impairment of heme synthesis in other tisues is not of concern until blood lead levels are reached greater than those associated with hematological effects. The air quality criteria document does point out that this effect has been established in other tissues and that other dose-response factors may apply.

The effect of lead on the formation of heme is not limited to the hematopoietic system. Experimental animal

studies have shown a lead effect on the heme-requiring protein, cytochrome P-450, an integral part of the hepatic mixed-function oxidase (chapter 11), the systemic function of which is detoxification of exogenous substances. Heme synthesis inhibition also takes place in neural tissue. (P.13-5)

In summary, the criteria document states:

> Elevation in protoporphyrin is considered not only to be a biological indicator of impaired mitochondrial function of erythroid tissue but also an indicator of accumulation of substrate for the enzyme ferrochelatase. It therefore has the same pathophysiological meaning as increased urinary δ-ALA (vide supra). For these reasons, accumulation of protoporphyrin has been taken to indicate physiological impairment in humans, and this clinical consensus is expressed in the 1975 Statement of the Center for Disease Control (CDC), USPHS. The criterion used by CDC to indicate an effect of lead on heme function is an FEP level of 60 μg/dl in the presence of a blood lead level above 30 μg/dl whole blood.
>
> More recent information relating to threshold of lead effects indicates that FEP levels begin to increase at a blood lead value of 15 to 20 μg Pb/dl blood in children and women and, at a somewhat higher value, 20 to 25 μg Pb/dl blood, in adult men. (P.13-5.)

EPA concludes that the state of elevated EP must be regarded as potentially adverse to the health of young children. While the onset or a mild experience of this condition may be tolerated by an individual, as with other subclinical manifestations of impaired function, it is a prudent public health practice to exercise corrective action prior to the appearance of clinical symptoms. The criteria document reports that symptoms of anemia in chidren may occur at blood lead levels of 40 μg/dl. EPA has adopted 30 μg Pb/dl as a maximum safe blood lead level for individual children.

The Blood Lead Threshold for Elevated Erythrocyte Protoporphyrin

Comments provided by ten organizations challenged EPA's conclusion that the threshold for the elevation of EP occurs in children at a blood lead level of 15 μg/dl. Evidence offered for a higher threshold included:

1. The threshold accepted by EPA is based on a study in which an inappropriate statistical technique, probit analysis, was employed.

2. Application of a more appropriate technique, segmented line analysis, results in a higher threshold.

3. The study in question excluded data on children with blood lead levels in excess of 30 μg/dl.

4. Other investigators have reported higher thresholds.

Comments in support of the 15 μg/dl threshold maintained:

1. It is proper to exclude values considered abnormal if the intent of the analysis is to determine an unbiased effect threshold.

2. Other studies have reported thresholds with error bands which include 15 μg/dl.

3. Probit analysis is an appropriate technique and differs only slightly from the results obtained from segmented line analysis.

Agency Response

EPA agrees that the segmented line technique provides a more accurate estimate of the correlation threshold of EP elevation with increasing blood lead, about 16.7 μg Pb/dl, and for this reason considered changing its judgments as to the maximum safe blood lead level for a population of children. However, as the target geometric mean for a population is increased, a greater percentage of children in the population

will exceed the maximum safe individual level of 30 μg Pb/dl. EPA estimates that at a population geometric mean of 15 μg Pb/dl, 99.5 percent of children will be below 30 μg Pb/dl. At 16.7 μg Pb this percentage falls to 98.7. EPA regards the number of children predicted to be below 30 μg Pb/dl as the critical health consideration. For this reason, EPA has maintained its estimate of a geometric mean of 15 μg Pb/dl as the target for population blood lead.

The Incidence of Health Effects in Populations Residing in the Vicinity of Industrial Sources of Lead Particulate Emissions

Several comments cited situations in which proximity to significant point sources of airborne lead emissions appear to have little or no health impact on resident populations. This was taken to imply that the air standard was not necessary to protect public health.

Agency Response

EPA acknowledges the variability of the impact of exposure to air lead on the potential for adverse health consequences. It is clear that direct exposure to air lead is only one of the routes through which human exposure occurs. It is for this reason that the Agency has accepted the concept that only a portion of the safe population mean blood lead level should be attributable to air lead exposure. The presence or absence of health effects in an exposed population is influenced by a variety of factors including: Meteorology, terrain characteristics, geological and anthropological history, personal and domestic hygiene, the occupations of the population members, and the food and nonfood materials with which they come into contact. Taking into account such variability, it remains the Agency's belief that airborne lead directly and indirectly contributes to the risk of adverse health consequences and that sufficient clinical and epidemiological evidence is available to form a judgment as to the extent of this contribution. This evidence includes epidemiological

studies showing higher blood lead levels in urban areas where air lead levels were elevated in comparison to rural areas. There have also been a number of studies linking elevated blood lead levels to industrial sources of lead emissions. With regard to the 1972 study at El Paso, Tex., by the Center for Disease Control, the criteria document reports:

> It was concluded that the primary factor associated with elevated blood lead levels in the children was ingestion or inhalation of dust containing lead. Data on dietary intake of lead were not obtained because the climate and proximity to the smelter prevented any farming in the area. It was unlikely that the dietary lead intakes of the children from near the smelter and farther away were significantly different. (P.12-15.)

With regard to the report of Yankel et al. at Kellogg, Idaho, the criteria document states:

> Five factors influenced, in a statistically significant manner, the probability of a child developing an excessive blood lead level:
>
> 1. Concentrations of lead in ambient air ($\mu g/m^3$)
>
> 2. Concentration of lead in soil (ppm).
>
> 3. Age (years)
>
> 4. Cleanliness of the home (subjective evaluation coded 0, 1, and 2, with 2 signifying dirtiest).
>
> 5. General classification of the parents' occupation (dimensionless).

Although the strongest correlation found was between blood lead levels and air lead level, the authors concluded that it was unlikely that inhalation of contaminated air alone could explain the elevated blood lead levels observed. (P.12-16.)

The Appropriate Relationship Between Lead in Air and Lead in Blood

Several commenters questioned the Agency's estimate that, for children, one microgram of lead per cubic meter air (μg Pb/m^3) results in an increase of two micrograms lead per deciliter blood (μg Pb/dl).

Agency Response

EPA has reviewed the studies discussed in the criteria document which report changes in blood lead levels with different air lead levels. The Agency believes that one of the strongest epidemiological studies is that by Azar et al. in which personal dosimeters were used to measure lead intake. This eliminated some of the uncertainty about the extent to which air quality observations accurately reflect actual exposure. From the Azar data, the relationship of lead in the air to lead in the blood, evaluated at 1.5 μg Pb/m^3 was 1:1.8. The Azar study was, however, limited to an adult population.

A clinical study of adults, Griffin et al., gives roughly the same conclusion for a group of adults confined to a chamber with controlled exposure to lead aerosol. This study was conducted over a three month period with control over lead ingestion. As air lead levels in the chamber were increased from 0.15 μg Pb/m^3 to 3.2 μg Pb/m^3 the air lead to blood lead relationship was 1:1.7.

Because children are known to have greater net absorption and retention of lead than adults, it is reasonable to assume that the air lead to blood lead relationship for this sensitive population, exposed to air lead levels in the range of the proposed standard, is equal to if not greater than for adults. EPA also notes that the air lead to blood lead relationship is nonlinear and may result in a higher ratio at lower air levels.

In an epidemiological study of children near a smelter, Yankel et al., the response of blood lead to air lead, averag-

ed over the exposure range, was 1.9. EPA believes that these studies as well as others reported in the criteria document, support the criteria document's conclusion that:

> Ratios between blood lead levels and air lead exposures were shown to range generaly from 1:1 to 2:1. These were not, however, constant over the range or air lead concentrations encountered. There are suggestive data indicating that the ratios for children are in the upper end of the range and may even be slightly above it. There is also some slight suggestion that the ratios for males are higher than those for females. (P.12-38.)

The Statistical Form and Period of the Standard

One commenter expressed the view that, due to the lognormal distribution of measured air lead, a not-to-be-exceeded standard of 1.5 $\mu g/m^3$, calendar month average, would require sources of air lead to achieve control of their emissions to a geometric monthly mean of 0.41 $\mu g/m^3$ in order to prevent the occurrence of a violation. Another comment expressed the opinion that with the normal operation of a 6-day sampling schedule, the number of samples which could be collected in the course of a calendar month would not provide a statistically valid estimate of the actual lead air quality for the period.

Several comments questioned the health basis for the selection of the calendar month averaging period.

EPA Response

EPA accepts the consensus of comments received on the scientific and technical difficulties presented by the selection of a calendar month averaging period. The agency believes that the key criterion for the averaging period is the protection of health of the sensitive population. In proposing the 1.5 $\mu g/m^3$ standard, EPA concluded that this air level as a ceiling would be safe for indefinite exposure of young children. The critical question in the determination of the

averaging period is the health significance of possible elevations of air lead above 1.5 $\mu g/m^3$ which could be sustained without violation of the average of 1.5 $\mu g/m^3$. In the proposed standard, EPA chose a monthly averaging period on the basis of a study showing an adjustment period of blood lead level with a change of exposure (Griffin et al.). Because of the scientific and technical difficulties of the monthly standard, EPA has reexamined this question and concludes that there is little reason to expect that the slightly greater possibility of elevated air lead levels within the quarterly period is significant for health. This conclusion is based on the following points:

(1) From actual ambient measurements, the distribution of air lead levels is such that where the quarterly standard is achieved, there is little possibility that there could be sustained periods greatly above the average value.

(2) While it is difficult to relate the extent to which a monitoring network actually represents the exposure situation for young children, it seems likely that where elevated air lead levels do occur, they will be close to point of mobile sources of lead air pollution. Typically, young children will not encounter such levels for the full 24-hour period reported by the monitor.

(3) There is medical evidence indicating that blood lead levels reequilibrate slowly to changes in air exposure. This serves to dampen the impact of a short-term period of exposure to elevated air lead.

(4) Direct exposure to air is only one of several routes of total exposure. This lessens the impact of a change in air lead on blood lead levels.

On balance, the Agency concludes that a requirement for the averaging of air quality data over calendar quarter will improve the validity of air quality data gathered without a significant reduction in the protectiveness of the standard.

The Appropriate Margin Of Safety

Several comments received by the Agency criticized the proposed standard for incorporating an excessive margin of safety. This criticism was based either on the view that the critical health effect, impaired heme synthesis, was not of health significance or on the view that EPA had employed conservative estimates of the several factors used in calculating the standard which when combined resulted in an excessively stringent standard.

Other comments were received which expressed concern that the standard had little or no margin of safety, particularly for certain subgroups within the general population of young children.

Agency Response

EPA does not agree that the impairment of heme synthesis is a physiological response to lead exposure that is without health significance. While EPA does not find that this impairment is necessarily serious to health at the point at which it first can be detected by the elevation of erythrocyte protoporphyrin, at a threshold in a range of 15-20 μg Pb/dl, the Agency does believe that above blood levels of 30 μg Pb/dl this effect has progressed to the extent that it should be regarded as an adverse health effect.

In determining the final ambient air standard for lead, EPA has used margin of safety considerations principally in establishing a maximum safe blood lead level for individual children at 30 μg Pb/dl and in determining the percentage of children to be placed below this maximum level, about 99.5 percent. Using these factors results in a target geometric mean population blood lead of 15 μg Pb/dl.

In establishing other factors used in calculating the standard, EPA has used margin of safety in the sense of making careful judgments based on available data, but these judgments have not been at the precautionary extreme of the range of data available to the Agency. In the case of the

geometric standard deviation (GSD), studies reviewed in the criteria document showed a range of 1.3 to 1.5. A standard based on a 1.5 GSD would be far more stringent than using 1.3. EPA took the 1.3, however, because of its concern that the total geometric standard deviation contains variation attributable to monitoring and analytical methodology. In estimating the relationship between air lead and blood lead to be 1:2, the Agency used an epidemiological study of children near a smelter, Yankel et al., where response of blood lead to air lead averaged over the exposure range was 1 to 1.9. In adopting 12 μg Pb as the part of blood lead attributable to nonair sources, EPA is concerned that typical levels for this component may be much greater, and that regulatory actions by other public health programs may be necessary to achieve a 12 μg level.

Because of the variability between individuals in a population experiencing a given level of lead exposure, EPA finds it is impossible to provide the same amount of margin of safety for all members in the sensitive population, or to define the margin of safety in the standard as a simple percentage. EPA does believe that the factors it has used in designing the standard provide an adequate margin of safety for a large proportion of the sensitive population. The Agency does not believe that this margin is excessively large or on the other hand that the air standard can protect everyone from elevated blood lead levels.

The Importance of the Respirable Fraction of Total Air Lead Level

The Agency received a number of comments expressing concern that, because only a fraction of airborne particulate matter is respirable, an air standard based on total air lead is unnecessarily stringent.

Agency Response

EPA agrees that some lead particles are too small or too large to be deposited in the respiratory system. EPA cannot conclude, however, that particles outside of the respirable range do not represent an exposure hazard. A significant component of exposure can be ingestion of materials contaminated by deposition of lead from the air. In addition to the indirect route of ingestion and absorption from the gastrointestinal tract, nonrespirable lead in the environment may, at some point, become respirable through weathering or mechanical action. EPA concludes, therefore, that total airborne lead, both respirable and nonrespirable fractions, should be addressed by the air standard.

The Economic Impact of the Proposed Standard

A number of commenters were critical of the Agency's economic impact assessment, and argued that the forecast underestimated the severity of the economic impact to certain lead industries.

Agency Response

The comments critical of the draft impact statement did not include data which would allow EPA to confirm the possibility of more severe economic impacts on certain source categories including primary and secondary lead smelters which could have difficulty in limiting emissions sufficiently to assure attaining the standard in their immediate vicinity. Under the Clean Air Act, the primary responsibility for implementing the standard is assigned to the States and each State is required to submit a plan to EPA demonstrating how attainment is to be achieved. The actual economic impacts of implementation are difficult to estimate at this time since, following promulgation, States will have 9 months to develop and submit these plans to EPA. The plans must demonstrate attainment as soon as practicable, but no later than 3 years following the date of plan approval. However, under certain

circumstances, States may request up to a 2-year extension of this deadline. Other sections of the Clean Air Act may be used with the Administrator's discretion to grant further extensions of compliance deadlines for impacted industrial facilities.

EPA cannot at this time accurately predict the impact of this standard, but with the timetable in the Act, sees no reason to expect imminent closure of any facility. The Agency is committed to developing accurate data for specific plants in cooperation with the industry and State agencies in order to avoid the imposition of unnecessary controls. EPA's principal concern, however, must be to follow the mandate of the Clean Air Act relating to the protection of the public health.

EPA believes that the economic impact assessment is a reasonable forecast of the economic consequences of implementation of the standard.

The Proposed State Implementation Plan (SIP) Regulations

A summary of comments and the Agency response is included in the preamble to the final regulations published elsewhere in this FEDERAL REGISTER.

The Federal Reference Method For Monitoring Lead Air Quality

A summary of comments and the Agency's disposition is included in the preamble to the final method published elsewhere in this FEDERAL REGISTER.

The Administrative Procedures Employed By EPA In The Development Of The Proposed Standard And The Provision For Public Participation

Two commenters requested that cross examination of witnesses be allowed in the post-proposal public hearing on the proposed standard and implementation regulations. EPA also received a request to postpone the public hearing and to extend the comment period, citing the need to complete ongoing studies.

Agency Response

Both the request for cross-examination and the extension of the comment period were denied by the Agency. With regard to the request for cross-examination, the Agency determined that, in light of the extensive review already conducted, cross-examination was not likely to produce new information or results that would justify such a significant departure from the normal rulemaking process. Also the existence of the normal comment period was sufficient to allow interested members of the public to raise questions concerning the Agency's determinations. Further, due to the extensive review opportunities available at all stages of the regulatory development, an extension of the comment period was not believed to be sufficiently necessary to further delay the schedule for preparation of the final rule.

Clarification Of Elements Of The Standard

From reviewing the comments received, EPA wishes to clarify the following points in the presentation of the rationale for the final standard:

(1) EPA is making a distinction between the blood lead level that is the threshold for detection of the biological effect, impaired heme synthesis, and the blood lead level at which this effect has progressed to an extent that it is regarded as adverse to health.

(2) EPA is making a distinction between estimating a maximum safe blood lead level for an individual child, and establishing a population target geometric mean blood lead level for the sensitive population.

(3) EPA is making a distinction between what the contribution to blood lead levels from nonair sources actually may be, and attributing a contribution from nonair sources for the purpose of standard setting.

Derivation Of The Numerical Level Of The Final Standard

EPA's objective in setting the level of the standard is to estimate the concentration of lead in the air to which all groups within the general population can be exposed for protracted periods without an unacceptable risk to health.

This estimate is based on EPA's judgment in four key areas:

(1) Determining the "sensitive population" as that group within the general population which has the lowest threshold for adverse effects or greatest potential for exposure. EPA concludes that young children, aged 1 to 5, are the sensitive population.

(2) Determining the safe level of total lead exposure for the sensitive population, indicated by the concentration of lead in the blood. EPA concludes that the maximum safe level of blood lead for an individual child is 30 μg Pb/dl and that population blood lead, measured as the geometric mean, must be 15 μg Pb/dl in order to place 99.5 percent of children in the United States below 30 μg Pb/dl.

(3) Attributing the contribution to blood lead from nonair pollution sources. EPA concludes that 12 μg Pb/dl of population blood lead for children should be attributed to nonair exposure.

(4) Determining the air lead level which is consistent with maintaining the mean population blood lead level at 15 μg Pb/dl. Taking into account exposure from other sources (12 μg Pb/dl) EPA has designed the standard to limit air contribution after achieving the standard to 3 μg Pb/dl. On the basis of an estimated relationship of air lead to blood lead of 1 to 2, EPA concludes that the ambient air standard should be 1.5 μg Pb/m^3.

Each of these four areas is discussed further in the following sections.

Sensitive Population

EPA believes that the health of young children is at particular risk from lead exposure. This is because children have a greater physiological sensitivity to the effects of lead than do adults and may have greater exposure to environmental lead from playing in contaminated areas. Other sensitive populations identified by EPA include those occupationally exposed, and pregnant women and their fetuses. Comments received on the proposed standard did not challenge EPA's position that young children are the most sensitive population for determining the standard. A number of comments did point out that within the general population of children there were subgroups with enhanced risk due to genetic factors, dietary deficiencies, or residence in urban areas. EPA acknowledges the higher risk status of such groups but does not have information either in the air quality criteria or in the comments received for estimating a threshold for adverse effects separate from that of all young children. Concern about these high risk subgroups has, however, influenced EPA's determination of the percentage of the population of children (99.5 percent) to be maintained below 30 μg Pb/dl.

EPA continues to be concerned about the possible health risk of lead exposure for pregnant women and their fetuses. The stress of pregnancy may place pregnant women in a state more susceptible to the effects of lead, and transplacental transfer of lead may affect the prenatal development of the child. There is, however, insufficient scientific information for EPA to either confirm or dismiss this suggestion, or to establish that pregnant women and fetuses are more at risk than young children.

The Maximum Safe Exposure For Children

In determining the maximum safe exposure to lead for children, EPA has taken the measurement of blood lead as the indicator of total lead dose. There are other possible indicators of exposure, for example the level of zinc protopor-

phyrin (ZPP), but most health studies reported in the criteria document utilize blood lead levels as indications of the mobile body burden of lead. The criteria document reports the following table of effect thresholds for children with increasing blood lead levels.

Summary Of Lowest Observed Effect Levels in Young Children

	μg Pb/dl
δ-ALAD inhibition	10
Erythrocyte protoporphyrin elevation	15-20
Increased urinary δ-ALA excretion	40
Anemia	40
Coproporphyrin elevation	40
Cognitive (CNS) deficits	50-60
Peripheral neuropathies	50-60
Encephalopathic symptoms	80-100
	(P.13-8.)

The first physiological effect associated with increasing blood lead levels is the inhibition of the enzyme δ-aminolevulinic acid dehydratase (δ-ALAD), both in red blood cells (erythrocytes), and in cells in other tissues. This enzyme catalyzes the condensation of two molecules of δ-aminolevulinic acid (δ-ALA) to form porphobilinogen, one of the components involved in the cellular synthesis of heme. The criteria document reports that the threshold for δ-ALAD inhibition in children is 10 μg Pb/dl.

At blood lead levels above 10 μg Pb/dl, the function of δ-ALAD is increasingly inhibited by lead. The criteria document states that 40 μg Pb/dl is the threshold for elevation of δ-ALA recognized as δ-ALA in the urine or δ-ALA-U, an indication that δ-ALA has begun to accumulate in cells.

EPA does not regard the inhibition of δ-ALAD above 10 μg Pb/dl as adverse to health because of the absence of evidence that there is an impairment of heme synthesis until a threshold of 40 μg Pb/dl is reached. The accumulation of δ-ALA above normal levels, indicated by δ-ALA-U, is regarded as adverse to health, both because of impaired heme syn-

thesis, and the possibility that δ-ALA accumulation is itself toxic to cells.

The criteria document reports that above a threshold of 15-20 μg Pb/dl there is an elevation of protoporphyrin in erythrocytes. Protoporphyrin is an organic chemical compound used by all cells in the production of heme. In the final stage of heme synthesis, erythorocyte protoporphyrin (EP) and iron are brought together in the cell mitochondria. In the presence of lead, this step is blocked, possibly by inhibition of enzyme ferrochelatase or by interference in the transport of iron across the mitochondrial membrane. Without incorporation into heme, the levels of protoporphyrin in the cell become elevated.

From review of the information provided by the air quality criteria document as well as the evidence and arguments offered by medical professionals commenting on the proposed standard, EPA has concluded that the effects of lead on the cullular synthesis of heme, as indicated by elevated erythrocyte protoporphyrin, are potentially adverse to the health of young children. This appears, however, to be a question of the degree to which the effect has progressed. EPA does not believe that there is significant risk to health at the point where the elevation of EP can first be correlated with an increase in blood lead (15 to 20 μg Pb/dl). On the other hand, EPA regards as clearly adverse to health the impairment of heme synthesis, and other effects of lead which result in clinical symptoms of anemia above 40 μg Pb/dl. These effects are followed quickly by the risk of nervous system deficits for some children with blood lead levels of 50 μg Pbdl.

EPA has concluded that the maximum safe blood lead level for an individual child is 30 μg Pb/dl. This is based on the following factors:

(1) The maximum safe blood lead level should be somewhat lower than the threshold for a decline in hemoglobin levels (40 μg Pb/dl).

(2) The maximum safe blood lead level should be at an even greater distance below the threshold for risks of nervous system deficits (50 μg Pbdl).

(3) The maximum safe blood lead level should be no higher than the blood lead range characterized as undue exposure by the Center for Disease Control of the Public Health Service, as endorsed by the American Academy of Pediatrics, because of elevation of erythrocyte protoporphyrin (above 30 μg Pb/dl).

(4) The maximum safe blood lead level for an individual need not be as low as the detection point for the initial elevation of EP (15-20 μg Pb/dl).

The criteria document points out that data from epidemiological studies show that the log values of measured individual blood lead values in a uniformly exposed population are normally distributed with a geometric standard deviation (GSD) of 1.3 to 1.5. Using standard statistical techniques, it is possible to use the geometric standard deviation to calculate the mean population blood lead level which would place a given percentage of the population below the level of an effects threshold. A GSD of 1.5 would result in a lower geometric mean, and a more stringent standard. However, because some of the variability in the GSD is from measurement systems, EPA has used a GSD of 1.3.

Recently, analysis of the data collected by New York City's Bureau of Lead Poisoning has shown that populations of children in the New York area consistently have distributions of blood lead values with a GSD of 1.4 to 1.5. With a geometric mean of 15.0 μg Pb/dl, a GSD of 1.4 results in about two percent of the population over levels of 30 μg Pb/dl. A GSD of 1.5 would place more than four percent over 30 μg Pb/dl. EPA is concerned that such results may imply that the standard is not as precautionary as it would be if the actual GSD was 1.3. However, the Agency's best estimate is that some of the GSD is from analytical and monitoring

variance, and for this reason, EPA is using the 1.3 value in calculating the final standard.

In EPA's view, use of the 99.5 percent range is not excessive. From 1970 statistics, there are approximately 20 million children in the United States below the age of 5 years, 12 million in urban areas, and 5 million in center cities where lead exposure may be high. Again, knowledge that there are special high risk groups of children within the general population deters EPA from considering lower percentages.

Contribution To Total Lead Exposure From Nonair Sources

In the proposed standard, EPA argued that the air standard should take into account the contribution to blood lead levels from lead sources unrelated to air pollution. No comments were received challenging this argument. EPA continues to base its calculation of the ambient air standard on the assumptions that, to an extent, the lead contribution to blood lead from nonair sources should be subtracted from the estimate of safe mean population blood lead. Without this subtraction, the combined exposure to lead from air and nonair sources would result in a blood lead concentration exceeding the safe level.

EPA notes that the level of the standard is strongly influenced by judgments about nonair contribution to total exposure, and that there are difficulties in attempting to estimate exposure from various lead sources. Studies reviewed in the criteria document do not provide detailed or widespread information about the relative contribution of various sources to children's blood lead levels. Estimates can only be made by inference from other empirical or theoretical studies, usually involving adults. Also, it can be expected that the contribution to blood lead levels from nonair sources can vary widely, is probably not in constant proportion to air lead contribution, and in some cases may alone exceed the target mean population blood lead level.

In spite of these difficulties, EPA has attempted to assess available information in order to estimate the general contribution to population blood lead levels from air and nonair sources. This has been done with evaluation of evidence from general epidemiological studies, studies showing decline of blood lead levels with decrease in air lead, studies of blood lead levels in areas with low air lead levels, and isotopic tracing studies.

Studies reviewed by the criteria document show that the geometric mean blood lead levels for opulations of children are frequently above 15 μg Pb/dl. In studies reported, the range of mean population blood lead levels for children was from 16.5 μg Pb/dl to 46.4 μg Pb/dl with most studies showing mean levels greater than 25 μg Pb/dl (Fine, 1972; Landrigan, 1975; von Lindern, 1975). EPA believes that, for many of these populations, the contribution to blood lead levels from nonair sources may exceed the desired target mean blood lead level.

In a number of studies, reduction in air lead levels resulted in a decline in children's blood lead levels. A study of blood lead levels in children in New York City showed that children's mean blood lead levels declined from 30.5 μg Pb/dl from 1970 to 1976, while during the same period air lead levels at a single monitoring site fell from 2.0 μg Pb/dl to 0.9 μg/Pb (Billick, 1977). Studies at Omaha, Nebr. (Angle, 1977) and Kellogg, Idaho (Yankel, von Lindern, 1977) also show a drop in mean blood lead levels with declines in air lead levels. As air lead levels decline there appears to be a rough limit to the drop in blood lead levels.

EPA has also examined epidemiological studies in the criteria document where air lead exposure is low, and can be assumed to be a minor contributor to blood lead. These studies provide an indication of blood lead levels resulting from a situation where nonair sources of lead are predominant.

Studies Reporting Blood Lead Levels In Children Exposed To Moderate To Low Air Lead Levels

Investigator	Blood lead[1]	Air lead[2]	Comment
Hammer, 1972.....	11.6	0.1.....	Children in Helena, Mont.
Angle, 1974.....	14.4	0.14.....	Suburban Children ages 1 to 4 in Omaha, Nebr.
Goldsmith, 1974.....	13.7	0.2 to 0.7....	Children in Benecia, Calif.
		0.3 to 0.6....	Children in Crocket, Calif.
Johnson, Tillery, 1975.	10.2	0.6.....	Female children—mean age 9 in Lancaster, Calif.

[1]In micrograms of lead per deciliter.
[2]In micrograms of lead per cubic meter.

The range of mean blood lead levels in those studies is from 10.2 μg Pb/dl to 14.4 μg Pb/dl, with an average at 12.7 μg Pb/dl.

In addition to epidemiological investigations, EPA has reviewed studies that examine the source of blood lead by detecting characteristic lead isotopes. A study using isotopic tracing (Manton, 1977) suggests that for several adults in Houston, Tex., 7 to 41 percent of blood lead could be attributed to air lead sources. An earlier isotopic study (Rabinowitz, 1974) concluded that for two adult male subjects studied, approximately one-third of total daily intake of lead could be attributed to exposure to air lead levels of 1-2 μg Pb/m^3. While these results cannot be directly related to children, it is reasonable to assume that children may exhibit the same or higher percentages of air lead contribution to blood lead level because of a greater potential for exposure to indirect air sources, soil and dust.

From reviewing these areas of evidence, EPA concludes that:

1. In studies showing mean blood lead levels above 15 μg Pb/dl, it is probable that both air and nonair sources of lead contribute significantly to blood lead with the possibility that contributions from nonair sources exceed 15 μg Pb/dl.

2. Studies showing a sustained drop in air lead levels show a corresponding drop in blood lead levels, down to an apparent limit in the range of 10.2 to 14.4 μg Pb/dl.

3. Isotopic tracing studies show air contribution to blood lead to be 7-41 percent in one study and about 33 percent in another study.

In considering this evidence, EPA notes that if, from the isotopic studies, approximately two-thirds of blood lead is typically derived from nonair sources, a mean blood lead target of 15 μg Pb/dl would attribute 10 μg Pb/dl to non-air sources. On the other hand, the average blood lead level from the limited studies available where air exposure was low is 12.7 μg Pb/dl. In the absence of more precise information, EPA is calculating the lead standard based on the attribution of 12 μg Pb/dl of the blood lead level in children to lead sources unaffected by the lead air quality standard. EPA is aware that actual population blood lead levels, either individually or as a population mean, may exceed this benchmark. However, if EPA were to use a larger estimate of non-air contribution to blood lead, the result would be an exceptionally stringent standard, which would not address the principal source of lead exposure.

The Relationship Between Air Lead Exposure And Resulting Blood Lead Level

EPA has reviewed the studies discussed in the criteria document which report changes in blood lead levels with different air lead levels. The Agency believes that one of the strongest epidemiological studies is that by Azar et al., which

used personal dosimeters to measure lead intake. This eliminated some of the uncertainty about the extent to which air quality observations accurately reflect actual exposure. From the Azar data, the relationship of lead in the air to lead in the blood, evaluated at 1.5 μg Pb/m^3, was 1:1.8. The Azar study was, however, limited to an adult population.

A clinical study of adults, Griffin et al., gives roughly the same conclusion for a group of adults confined to a chamber with controlled exposure to lead aerosol. This study was conducted over a three month period with control over lead ingestion. As air lead levels in the chamber were increased from 0.15 μg Pb/m^3 to 3.2 μg Pb/m^3, the air lead to blood lead relationship was 1:17.

Because children are known to have greater net absorption and retention of lead than adults, it is reasonable to assume that the air lead to blood lead relationship for this sensitive population, exposed to air lead levels in the range of the proposed standard, is equal to if not greater than for adults. EPA also notes that the air lead to blood lead relationship is nonlinear which will result in a higher ratio at lower air levels.

In an epidemiological study of children near a smelter, Yankel et al., the response of blood lead to air lead, averaged over the exposure range, was 1.95. This study provided information on the relationship of blood lead to air lead over a very large range of air lead values. The air led values in the study are the result of a model calibrated by monitoring data. The relative error of the individual values, especially in the low range is larger than in the Azar study.

The authors of the study, Yankel and von Lindern, chose a log-linear model which provided a good fit to the data and gave an estimated slope of about 1.2 at an air lead of 1.5. However, EPA sees a problem with a log-linear model in that it forces a lower slope at low air lead values and a higher slope at higher lead values. This is in direct contradiction to the Azar and the Griffin studies, both of which indicate higher slopes at lower air lead values.

Because of the uncertainties in the low air lead values in the Idaho study, EPA felt that the calculation of an average slope or ratio over the entire range of data would be a moderate compromise. The calculation of an average slope gives a value of 1.95. EPA believes that these studies as well as others reported in the criteria document support the document's conclusion that:

> ratios between blood lead levels and air lead exposure were shown to range generally from 1:1 to 2:1. These were not, however, constant over the range of air lead concentrations encountered. There are suggestive data indicating that the ratios for children are in the upper end of the range and may even be slightly above it. There is also some slight suggestion that the ratios for males are higher than those for females. (pp. 12-38.)

Calculation Of The Air Standard

EPA has calculated the standard based on the conclusions reached in the previous sections:

1. Sensitive population: Children, ages 1-5.

2. Health basis: Maximum safe blood lead level for individual children is 30 μg Pb/dl based on concern for impaired heme synthesis above 30 μg Pb/dl and margin of safety for anemia above 40 μg Pb/dl and nervous system deficits above 50 μg Pb/dl.

3. Maximum safe geometric mean blood lead for children based on placing 99.5 percent of the sensitive population below the 30 μg Pb/dl level of concern: 15 μg Pb/dl.

4. Estimate of blood lead level attributed to non-air sources: 12 μg Pb/dl.

5. Allowable contribution to blood lead from air sources after achieving the standard: 15 μg Pb/dl-12 μg Pb/dl = 3 μg Pb/dl.

6. Air lead concentration consistent with blood lead contribution from air sources: 3 μg Pb/dl × 1 μg Pb/m^3 air/2 μg Pb/dl blood = 1.5 μg Pb/m^3.

Selection Of The Averaging Period For The Standard

Based on comments received and consideration by the Agency, the proposed averaging period of a calendar month is extended to a calendar quarter. EPA believes that this change will significantly improve the validity of lead air quality data which will be gathered to monitor progress toward attainment without placing an undue burden of State and local environmental agencies, or significantly reducing the protectiveness of the standard.

The Agency believes that the key criteria for the averaging period is the protection of the health of the sensitive population. In proposing the 1.5 Mg Pb/m³ standard, EPA concluded that this air level was safe for young children with an indefinite exposure period. The critical factor in the determination of the averaging period is the health significance of possible elevations of air lead above 1.5 Mg Pb/m³ which could be encountered for short periods without causing average levels to exceed the standard. In the proposed standard, EPA chose a calendar month averaging period on the basis of a study (Griffin et al.) showing an adjustment period of blood lead level with a change in exposure. Because of the scientific and technical difficulties of the monthly standard, EPA has reexamined this question and concluded that there is little reason to expect that the slightly greater possibility of elevated air lead levels sustainable by the calendar quarter standard is significant for health. This conclusion is based on the following factors:

(1) From actual ambient measurements, there is evidence that the distribution of air lead levels is such that if the quarterly average was achieved there is little possibility that there could be sustained periods greatly above the average value.

(2) While it is difficult to relate the extent to which a monitoring network actually represents the exposure situation for young children, it seems likely that where elevated air lead levels do occur, they will be close to point or mobile sources.

Typically, young children will not encounter such levels for the full 24-hour period reported by the monitor.

(3) There is medical evidence indicating that blood lead levels reequilibrate slowly to changes in air exposure. This serves to dampen the impact of a short-term period of exposure to elevated air lead.

(4) Direct exposure to air is only one of several routes of total exposure. This lessens the impact of a change in air lead on blood lead levels.

On balance, the Agency concludes that a requirement for the averaging of air quality data over a calendar quarter will improve the validity of air quality data gathered without a significant reduction in the protectiveness of the standard.

Margin Of Safety

The Clean Air Act instructs EPA to set the level of an ambient air quality standard at a level which protects the public health with a margin of safety. One approach to using margin of safety is to estimate the air concentration of a pollutant that is the threshold for the first adverse effect detected with the increasing air levels, and then set the air standard at a somewhat lower level. The extent of the safety margin between the standard and the estimated threshold for adverse effects is influenced by such factors as the severity or irreversibility of effects, the degree of uncertainty about known or suspected health effects, the size of the population at risk, and possible interactions of several pollutants in potentiating health effects. While the margin of safety is based on available scientific information, this factor is judgmental in that the Administrator must weigh the acceptability of estimated risk.

Estimating an appropriate margin of safety for the air lead standard is complicated by the multiple sources and media for lead exposure. Because of this, EPA has elected to use margin of safety considerations in estimating the max-

imum safe level for blood lead, and the percentage of the sensitive population to be placed below this level, rather than making a final adjustment to concentration of lead in the air. EPA has adopted 30 μg Pb/dl as the maximum safe blood lead level for individual children, and the air standard is calculated to maintain most children below this target. On the basis of information developed in the criteria document and from public comment, blood lead levels between 30 and 40 μg Pb/dl are associated with impairments of the heme synthetic pathway which EPA regards as adverse to health. Blood lead levels above 40 μg Pb/dl are associated with a decline in hemoglobin levels, and levels above 50 μg Pb/dl are associated with the risk of nervous system deficits for some children. With a geometric mean population blood of 15 μg Pb/dl lead, most children will be well below these thresholds, but a small percentage can be expected to have blood lead levels of concern.

Because of the variability between individuals in a population experiencing a given level of lead exposure, EPA finds that it is not possible to provide the same amount of margin of safety for all members in the sensitive population, or to define a margin of safety in this standard as a simple percentage. In developing the numerical level of the standard, EPA used evidence in the criteria document that the blood lead levels for individuals in a given population of children are log-normally distributed. The statistical properties of this distribution make it possible to calculate the percentage of the population which will fall below any given blood lead level. Individuals at each of these levels would have a different margin of safety below the maximum safe blood lead level. As a rough example, with a population of children with a geometric mean blood lead of 15 μg Pb/dl, 86 percent of the children would be below 20 μg Pb/dl, 97.5 percent would be below 25 μg Pb/dl and 99.5 percent would be below 30 μg Pb/dl. Assuming a population of children in central urban areas where air lead was at the standard level, 693,000 children would be over 20 μg Pb/ dl, 126,500 over 25 μg Pb/dl, and 20,605 above 30 μg Pb/dl.

In determining the appropriate margin of safety, the Agency has also included consideration of the following factors:

(1) In addition to the health effects discussed, the "Air Quality Criteria for Lead" report multiple biological involvements of lead in practically all cell types, tissues, and organ systems. The significance for health of these has not been fully studied.

(2) There are no beneficial effects of lead at current environmental levels.

(3) EPA has incomplete data about the extent to which children are indirectly exposed to lead from air lead which moves to other environmental media, such as water, soil and dirt, and food.

(4) Lead is chemically persistent and with continued uncontrolled emissions will continue to accumulate both in human tissue and in the environment.

(5) There is a possibility that lead exposure resulting in blood lead levels previously considered safe may in fact influence the neurological development and learning abilities of the young child. EPA does not have evidence, however, that provides more than a suggestion that this could occur at blood lead levels below 30 Pb/dl for individual children.

Impact Of Lead Dustfall On Blood Lead

In the preamble for the proposed air standard for lead, EPA pointed out that the significance of dust and soil lead as indirect routes of exposure has been of particular concern in the case of young children. Play habits and mouthing behavior between the ages of 1 and 5 have led to the conclusion that greater potential may exist in these children for ingestion and inhalation of the lead available in contaminated dust and soil. EPA is also concerned that the deposition of lead particles can lead to general contamination of the environment and increased lead exposure from surface waters and foodstuffs.

Studies reviewed in the criteria document indicate a correlation between soil and dust levels and children's blood lead levels in highly contaminated environments (Yankel and von Lindern, 1977: Barltrop, 1974; Galke, in press). The lead threshold for concern has been reported as 1,000 parts per million (ppm) in soil (Yankel and von Lindern, 1977). At levels of between 500 and 1,000 ppm in soil, the criteria document concludes that blood lead levels begin to increase. A twofold increase in soil concentration in this range is predicted to result in a 3-6 percent rise in blood lead levels. Below 500 ppm lead in soil, no correlation has been observed with blood lead levels.

The normal background for lead in soil is cited in the criteria document as 15 ppm. Due to human activities, the average levels in most areas of the United States are considerably higher. Soil studies conducted by EPA's Office of Pesticides Programs from 1974 to 1976 in 17 urban areas reported only 3 cities with arithmetic mean concentrations in excess of 200 ppm, with the highest value 537 ppm. Concentrations in the soils surrounding large point sources of lead emissions, or heavily travelled roads may reach many thousand ppm.

Because of the many factors involved, EPA is unable to predict the relationship between air lead levels, dustfall rates, and resulting soil accumulation. Complicating factors include: Particle size distribution, rainout, other meteorological factors, topographical features affecting deposition, and removal mechanisms.

EPA believes, however, that significant impacts on blood lead of soil and dust lead are mainly limited to areas of high soil concentration (in excess of 1,000 ppm) around large point sources and heavily travelled roads. Evidence suggests that soil lead levels in areas with air lead levels in the range of the standard are below the threshold for lead health impact (Johnson, Tillery, 1975; Johanson, 1972; EPA, 1975 Air Quality Data and Soil Levels).

Comments received on the proposed standard argued that the lead air standard should be limited to respirable size lead particulate matter, as larger particles would fall to the ground without being deposited or absorbed in the lung. EPA has decided not to accept this recommendation because, as discussed above, larger particles can contribute to lead dose by human ingestion of airborne particles, by contamination of other environmental media, or by eventual reduction to respirable size by mechanical action or weathering.

Welfare Effects

Comments received on the proposed lead air quality standard did not address the issue of welfare effects or the need for a secondary air quality standard more restrictive than the primary standard. EPA maintains its position that the primary air quality standard will adequately protect against known and anticipated adverse effects on public welfare. EPA does not have evidence that a more restrictive secondary standard would be justified.

Available evidence cited in the criteria document indicates that animals do not appear to be more susceptible to adverse effects from lead than man, nor do adverse effects in animals occur at lower levels of exposure than comparable effects in humans.

Lead is absorbed but not accumulated to any great extent by plants from soil. Lead is either unavailable to plants or is fixed in the roots and only small amounts are transported to the above ground portions. Lead may be deposited on the leaves of plants and present a hazard to grazing animals. Although some plants may be susceptible to lead in the natural environment, it is generally in a form that is largely nonavailable to them.

There is no evidence to indicate that ambient levels of lead result in significant damage to manmade materials. Effects of lead on visibility and climate are minimal.

Based on such data, EPA promulgates the secondary air quality standard for lead at 1.5 μg Pb/m^3, calendar quarter average.

Economic Impact Assessment

As required by Executive Orders 11821 and 12044, EPA has conducted a general analysis of the economic impact which might result from the implementation of the lead regulations. This analysis was not intended for nor was it used in the development or promulgation of the standard, and was issued for informational purposes only.

The economic impact assessment points out that the categories of sources likely to be affected by control of lead emissions are primary lead and copper smelters, secondary lead smelters, gray iron foundries, gasoline lead additive manufacturers, and lead storage battery manufacturers. This analysis further indicates that some primary and secondary lead smelters and copper smelters may be severely strained economically in achieving emission reductions that may be required in implementing the proposed air quality standard.

There are, however, uncertainties associated with evaluating the impact of attaining the standard. For smelters and foundries, attaining the standard may require control of fugitive lead emissions, i.e., those emissions escaping from individual process operations other than emissions from smoke stacks. Fugitive emissions are difficult to estimate, measure, and control; and it is also difficult to predict their impact on air quality near the facility. From the information available to EPA, nonferrous smelters may have great difficulty in achieving lead air quality levels consistent with the proposed standard in areas immediately adjacent to the smelter complex.

The change in averaging time from a monthly average to a calendar quarter average will affect the economic impacts associated with the lead standard because for a given level of the standard, a longer averaging period is theoretically less stringent than a shorter averaging period.

Other Lead Regulatory And Control Programs

EPA's ambient air quality standard is only one of a number of Federal, State, and local programs designed to limit exposure to lead.

In 1975, EPA promulgated the national interim primary drinking water regulation, setting a maximum contaminant level for lead. The standard, aimed at protecting children from undue lead exposure, was set at 50 MG Pb/liter. In 1977, the National Academy of Sciences concluded that a lead level at which adverse health effects are observed cannot be set with assurance at any value greater than 25 MG Pb/liter. The Office of Drinking Water is currently considering the need to revise the interim drinking water standard for lead.

Based on its toxicity, EPA has included lead on its list of priority water pollutants for which effluent guidelines are being developed under the Clean Water Act. Effluent guidelines are being developed for lead for nonferrous smelters, based on achievement of best available technology.

EPA's Office of Pesticide Programs has promulgated regulations based on the toxicity of lead which require the addition of coloring agents to the pesticide lead arsenate and specify disposal procedures for lead pesticides. Use of lead in pesticides is a small and decreasing proportion of total lead consumption in the United States.

The Resource Conservation and Recovery Act (RCRA) of 1976, through which EPA is to establish standards on how to treat, dispose, or store hazardous wastes, provides a means for specifying how used crankcase oil and other waste streams containing lead should be recycled or safely disposed of. Regulatory actions related to wastes containing lead are currently being developed under subtitle C of RCRA.

EPA has regulations for reducing the average lead content in the total gasoline pool to 0.5 grams/gallon by October 1, 1979, and regulations providing for lead-free gasoline required for cars equipped with catalytic converters and other vehicles certified for use of unleaded fuel. The former regula-

tions are based on reducing exposure to airborne lead to protect public health. Other EPA actions which result in the reduction of airborne lead levels include ambient standards and State implementation plans for other pollutants such as particulate matter and sulfur dioxide and new source performance standards limiting emissions of such pollutants. Existing and new sources of particulate matter emissions generally use control techniques which reduce lead emissions as one component of particulate matter.

The Occupational Safety and Health Administration proposed regulations in 1975 to limit occupational exposure to lead to 100 μg Pb/m^3 8-hour time-weighted average. The exposure limit was based on protecting against effects, clinical or subclinical, and the mild symptoms which may occur below 80 μg Pb/dl, providing an adequate margin of safety. The level of 100 μg Pb/m^3 is anticipated to limit blood lead levels in workers to a mean 40 μg Pb/dl and a maximum of 60 μg Pb/dl. OSHA is presently reviewing the latest information on lead exposure and health effects in preparation for promulgation of the workplace standard for lead.

The Department of Housing and Urban Development (HUD) has requirements for reducing human exposure to lead through the prevention of lead poisoning from ingestion of paint from buildings, especially residential dwelling. Their activities include (1) prohibition of the use of lead-based paints on structures constructed or rehabilitated through Federal funding and on all HUD-associated housing; (2) the elimination of the immediate hazard from lead-based paint; (3) notification of purchases of HUD-associated housing constructed prior to 1950 which may contain lead-based paint; and (4) research activities to develop improved methods of detection and elimination of lead-based paint hazards, and the nature and extent of lead poisoning.

The Consumer Product Safety Commission (CPSC) promulgated regulations in September 1977 which ban: (1) Paint and other surface coating materials containing more than 0.06

percent lead; (2) toys and other articles intended for use by children bearing paint or other similar surface coating material containing more than 0.06 percent lead; and (3) furniture coated with materials containing more than 0.06 percent lead. These regulations are based on CPSC's conclusion that it is in the public interest to reduce the risk of lead poisoning to young children from ingestion of paint and other similar surface-coating materials.

The Food and Drug Administration (FDA) adopted in 1974 a proposed tolerance for lead of 0.3 ppm in evaporated milk and evaporated skim milk. This tolerance is based on maintaining children's blood lead levels below 40 μg Pb/ dl. FDA has also proposed an action level of 7 μg Pb/ml for leachable lead in pottery and enamelware, although the exact contribution of such exposure to total human dietary intake has not been established.

The Center for Disease Control (CDC) concluded in 1975 that undue or increased lead absorption exists when a child has confirmed blood lead levels of 30-70 μg Pb/dl or an EP elevation of 60-189 μg Pb/dl except where the elevated EP level is caused by iron deficiency.

In developing the lead air standard, EPA has estimated both individual and population blood lead levels which it regards as safe targets. The Agency believes that these targets do not necessarily serve as precedents for other regulatory programs. There are three reasons for this view:

(1) These targets were selected on the basis of what the Clean Air Act requires. Other programs have other legislative requirements which would lead to adoption of different but equally legitimate goals.

(2) The scientific data provided by the air quality criteria allow comparison of air levels with blood lead levels, but analogous information is not available for other media. At this time, there does not appear to be the same extent of information about the impact on blood lead of lead in food,

water, and nonfood ingested items. Because of this, FDA, CPSC and other EPA standards have been based on estimates of acceptable daily dose rather than on blood lead targets.

(3) Studies currently underway may provide new information relevant to estimating safe levels of lead exposure.

Comments By Other Federal Agencies

Comments on the proposed lead air quality standard were received from eight Federal Agencies. Five of the Agencies endorsed the air standard while three of the Agencies commented on specific issues and neither endorsed nor opposed the standard. The Center for Disease Control and the U.S. Public Health Service voiced support for the proposed standard of 1.5 μg Pb/m^3 and urged basing the decision on the standard solely on considerations of public health. CDC is fully satisfied that EP elevation does indeed represent a subclinical manifestation of lead toxicity and that young children are the population most at risk from lead exposure, while some subgroups of children are at special risk to lead because of conditions such as malnutrition, genetic factors, or iron deficiency.

The Consumer Product Safety Commission endorsed the approach and some of the judgments made in arriving at the proposed air standard. CPSC concurred with the position that children are the population at enhanced risk to lead exposure, and that the goal of a mean population blood lead level for children of 15 μg Pb/dl is sufficiently low to be protective of the population at enhanced risk of exposure. CPSC views the selection of EP elevation as the adverse health effect of concern as open to challenge and suggests basing the standard on a more generally recognized severe health effect. CPSC concurs that the contribution of nonair sources to lead body burden must be evaluated in setting the air standard and suggests that a larger nonair contribution, such as 13.5 μg Pb/dl used in the California standard, might be considered.

The Food and Drug Administration commended EPA's proposal of an ambient air quality standard for lead. FDA agrees that children aged 1-5 years old comprise the most critically sensitive population. FDA concurs that 15 μg Pb/dl is a reasonable maximum blood lead level to use as an average national goal for children aged 1 to 5, although FDA suggests that for young children the margin of safety is disturbingly narrow. The division of the 15 μg Pb/dl into 12 μg Pb/dl for nonair sources and 3 μg Pb/dl for air sources was not unreasonable in FDA's view.

The Occupational Safety and Health Administration endorsed EPA's proposed standard for lead and agrees with EPA that 15 μg Pb/dl as an average national blood lead level goal for young children is reasonable. OSHA views their proposed standard of 100 μg Pb/m^3, 8-hour time-weighted average, and their establishment of 40 μg Pb/dl as the threshold effect level for workers as consistent with the EPA proposed standard.

The Department of Transportation (DOT) endorsed the proposed standard of 1.5 μg Pb/m^3. Based on an analysis of the impact of the proposed standard on the highway program, DOT concluded that it is highly probable that transportation-related violations of the proposed standard would be limited to large urban areas.

In commenting on the proposed standard, the Department of the Interior (DOI) expressed concern that the burden for meeting the proposed standard will fall primarily on lead and copper smelters and battery manufacturers, and commented on the impact of lead dustfall on ground water quality. The Tennessee Valley Authority provided specific comments on the proposed State implementation plan regulations and the proposed Federal reference method. The Department of Commerce offered comments on the potential impacts of the standard, pointing out that more consideration should be given to the potential impact of the standard on the petroleum industry.

The Federal Reference Method

The reference method for the determination of lead in suspended particulate matter collected from ambient air describes the appropriate techniques for determining the concentration of lead and its compounds as measured as elemental lead in the ambient air. A total of eight organizations submitted written comments on the method and two persons made comments at EPA's February public hearing on the proposed air quality standard. Since proposal of the Federal reference method for lead, EPA has completed additional testing of the method and added new information on the precision of the extraction analysis procedure.

Two of the commenters recommended the addition of a nitric plus hydrochloric acid extraction procedure. The extraction procedure of the proposed method contains only nitric acid. Use of a mixed acid procedure would permit the analyst to quantitatively extract more metals than just lead, thereby allowing him to analyze the same extract for more than one metal. The analysis for lead would not be affected. EPA agrees that a mixed acid extraction procedure should be added, and the revised method contains a mixed nitric-hydrochloric acid extraction procedure.

One commenter questioned the reliability of the air volume measured in the sampling procedure because of differences between initial and final flow rates caused by buildup of particulate matter on the collecting filter. The method of sampling specifies that initial and final flow rates must fall between 40 and 60 cubic feet per minute and variations within this range cause only a slight error. If the flow rate specification is not met, the sample should be voided. For these reasons, EPA believes the air volume measurement does not suffer unduly from inaccuracies.

A question was raised as to the effect of variation in lead content across the filter of the collected sample on lead analysis, since the method calls for analysis of only one strip or one-twelfth of the filter. Our work has shown that strips

taken from different positions within the filter can, on occasion, produce different lead values, but the effect appears to be significant only when sampling near a heavily traveled roadway. The proposed method recommends analyzing additional strips, when sampling near a roadway, to minimize this error.

One commenter pointed out that the proposed sampling procedure does not collect gaseous (organic) lead compounds and recommended that EPA consider requiring the use of a method for monitoring gaseous lead. As the criteria document states, reported ambient levels of gaseous lead are very low and EPA has determined that the effort required to carry out the difficult task of monitoring for ambient gaseous lead is not justified in view of the extremely low concentration.

It was pointed out in the preamble to the proposed method that other analytical principles would probably be handled by provision for approval of the equivalent methods (40 CFR Part 53) proposed elsewhere in this Federal Register. Two organizations submitted requests that alternate methods (X-ray fluorescence and anodic stripping voltametry) for lead analysis be declared equivalent to the reference method. These requests will be considered when the procedures for determining equivalency are promulgated.

The final Federal reference method is based on measuring the lead content of suspended particulate matter on glass fiber filters using high volume sampling. The lead is then extracted from the particulate matter with nitric acid facilitated by heat or by a mixture of nitric acid and hydrochloric acid facilitated by ultrasonication. Finally, the lead content is measured by atomic absorption spectrometry.

The reference method specified for lead measures the lead for a single sampling period by extraction of a portion of a high-volume glass fiber filter used to collect particulate matter over a 24-hour period. Some agencies may prefer to composite filter strips from a number of sampling periods and extract and analyze it for lead. This procedure is acceptable

provided the Agency shows that the compositing procedure results in the same average lead value as would be obtained from averaging individual values.

Dated: September 29, 1978.

Douglas M. Costle,
Administrator.

REFERENCES

Angle, C. R. and M. S. McIntire, Environmental controls and the decline of blood lead. Arch. Environ. Hlth. (in press.) 1977.

Azar, A., R. D. Snee, and K. Habibi. An Epidemiologic Approach to Community Air Lead Exposure Using Personal Air Samplers. Environmental Quality and Safety, Supplement Vol II—Lead 254-288 (1975).

Barltrop, D., C. D. Strehlow, J. Thornton, and J. S. Webb. Significance of high soil concentrations for childhood lead burdens. Environ. Hlth. Persp. Expt. Iss. 7:75-84, 1974.

Billick, I. A. Curran, and D. Shier. Presentation to the U.S. EPA Lead Subcommittee of the Science Advisory Board, Washington, D.C., October 7, 1977.

Fine, P. R., C. W. Thomas, R. H. Suho, R. E. Cohnberg, and B. A. Flashner. Pediatric Blood Lead Levels A Study in 14 Illinois Cities of Intermediate Population. JAMA 221:1475-1479, September 25, 1972.

Johanson, W. C. and J. P. Luby. A Report on a Study to Determine the Blood Lead Levels in Dallas Children. Dallas Health Department, Dallas, Tex. 1972.

Johnson, D. E., J. B. Tillery, and R. J. Provost. Levels of platinum, palladium and lead in populations of Southern California. Environ. Health Persp. 12:27-33, 1975.

Landrigan, P. J., S. H. Gehlbach, B. F. Rosenblum, J. M. Shoults, et al. Epidemic Lead Absorption Near an Ore Smelter. The role of particulate lead. New England J. Med. 292:123-129, 1975.

Manton, W. I. Sources of Lead in Blood. Arch. Environmental Health, 32:149-156, 1977.

Rabinowitz, M. B. Lead contamination of the biosphere by human activity. A stable isotope study, PhD Thesis, University of California, Los Angeles, 1974, 120 pp.

U.S. Enviromental Protection Agency. Air Quality Criteria for Lead Office of Research and Development. Washington, D.C. 20460. EPA-450/8-77-017, December 1977.

von Lindern, I. and A. J. Yankel. Presentation to the Shoshone Heavy Metals Project Committee by Idaho Department of Health and Welfare, Boise, Idaho, September 4, 1975.

Yankel, A. J. and I. von Lindern. The Silver Valley lead study. The relationship of childhood lead poisoning and environmental exposure. J. Air Pollut. Cont. Ass., August 1977.

40 CFR Part 50 is amended by adding a new §50.12 and a new appendix G as follows:

§50.12 National primary and secondary ambient air quality standards for lead.

National primary and secondary ambient air quality standards for lead and its compounds, measured as elemental lead by a reference method based on appendix G to this part, or by an equivalent method, are: 1.5 micrograms per cubic meter, maximum arithmetic mean averaged over a calendar quarter.

(Secs. 109, 301(a) Clean Air Act as amended (42 U.S.C. 7409, 7601(a)).)

APPENDIX C

Excerpt from testimony of Dr. Herbert L. Needleman before EPA's public hearing on the proposed national ambient air quality standard for lead, February 15, 1978.

> "It is critical to me to reduce the blook levels of the vulnerable segments of our population to the lowest level that is acheivable. Because of biologic variations, it is also clear that if we were able to reduce the mean blood level of urban children to 15 micrograms per deciliter, about 10 percent of the population would have blood levels greater than 21 micrograms per deciliter, and 1 percent of the population would have blood levels greater than 27 percent, 27 micrograms per deciliter. That's a lot of children. It is critical, therefore, that the mean population blood level be below 15 micrograms per deciliter."

The above statement appears at p. 107 of the hearing transcript, and is reproduced at p. 1624 of the Joint Appendix filed in the Court of Appeals.

APPENDIX D

Excerpt from testimony of Dr. Sergio Piomelli before EPA's Science Advisory Board, Subcommittee on Scientific Criteria for Environmental Lead, January 31, 1977.

> "I believe it is extremely important if this document has to be the base for the recommendation for lead criteria to be promulgated later from EPA, that it should be objective evidence. I believe very strongly that if objective evidence is presented, that the standard of lead in the air should not be any greater than one microgram per cubic meter."

The above statement appears at p. 59 of the hearing transcript, and is reproduced at p. 188 of the Joint Appendix filed in the Court of Appeals.

PREVIOUS PAGE WAS BLANK